



US008439946B2

(12) **United States Patent**
Miller et al.

(10) **Patent No.:** **US 8,439,946 B2**
(45) **Date of Patent:** ***May 14, 2013**

(54) **SUTURE ANCHOR HAVING A SUTURE ENGAGING STRUCTURE AND INSERTER ARRANGEMENT**

(75) Inventors: **M. Todd Miller**, San Jose, CA (US);
Chad Wayne Lewis, Layton, UT (US);
David Eloy Quiñones Morales, Arroyo, PR (US)

(73) Assignee: **Stryker Corporation**, Kalamazoo, MI (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/476,525**

(22) Filed: **May 21, 2012**

(65) **Prior Publication Data**

US 2012/0232590 A1 Sep. 13, 2012

Related U.S. Application Data

(63) Continuation of application No. 12/380,891, filed on Mar. 4, 2009, now Pat. No. 8,197,511, which is a continuation-in-part of application No. 11/903,738, filed on Sep. 24, 2007.

(51) **Int. Cl.**
A61B 17/04 (2006.01)

(52) **U.S. Cl.**
USPC **606/232**

(58) **Field of Classification Search** **606/232**
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

146,023 A	12/1873	Russell
197,933 A	12/1877	Harvey
2,570,465 A	10/1951	Lundholm
3,233,500 A	2/1966	DeVellier
3,997,138 A	12/1976	Crock et al.
4,175,555 A	11/1979	Herbert
4,340,184 A	7/1982	Poss
4,507,817 A	4/1985	Staffeld
4,537,185 A	8/1985	Stednitz
4,632,100 A	12/1986	Somers et al.
4,640,271 A	2/1987	Lower
4,738,255 A	4/1988	Goble et al.
4,741,330 A	5/1988	Hayhurst
4,854,311 A	8/1989	Steffee
4,863,383 A	9/1989	Grafelmann
4,870,957 A	10/1989	Goble et al.
5,037,422 A	8/1991	Hayhurst et al.
5,047,030 A	9/1991	Draenert

(Continued)

FOREIGN PATENT DOCUMENTS

AU	0784963 B2	11/2002
CA	2 386 621 A1	11/2002

(Continued)

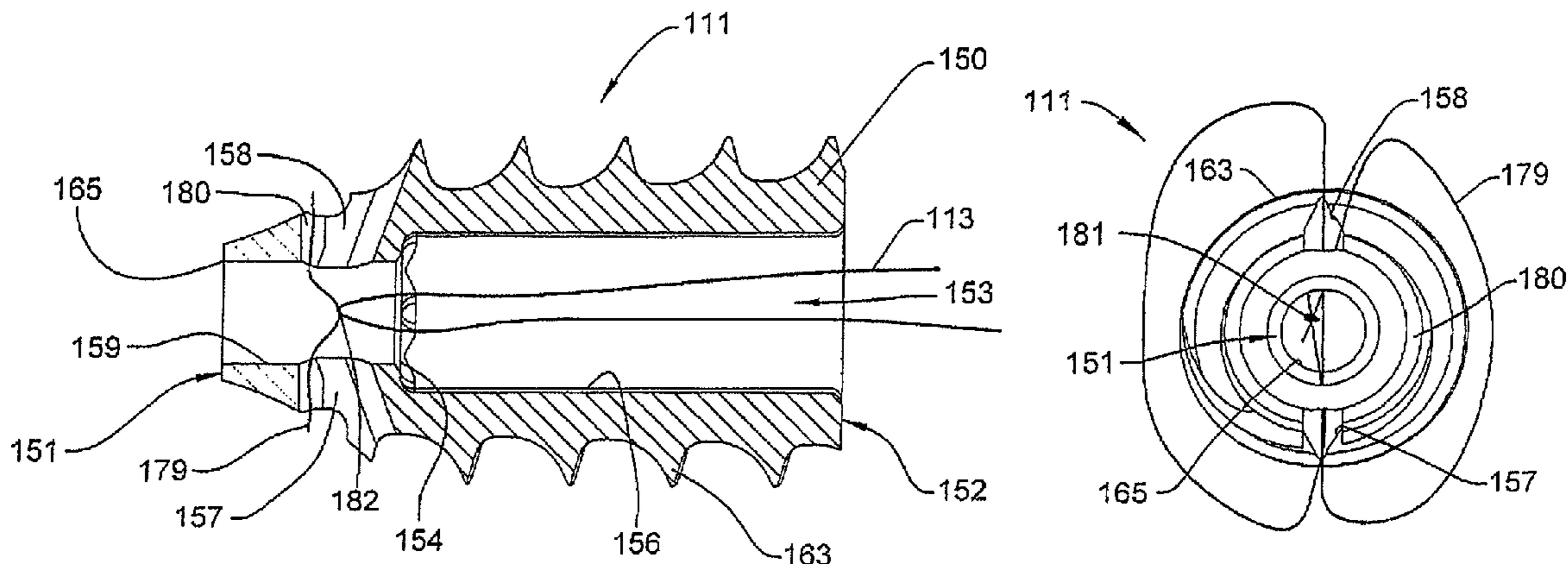
Primary Examiner — Melanie Tyson

(74) *Attorney, Agent, or Firm* — Flynn, Thiel, Boutell & Tanis, P.C.

(57) **ABSTRACT**

A suture anchor and inserter arrangement, including a suture anchor for implanting in hard tissue, such as bone, and an inserter device for installing the suture anchor in hard tissue. The suture anchor carries thereon a suture-engaging structure formed as a loop, which loop defines an attachment location for a working suture associated with the inserter device so as to attach the working suture to the suture anchor.

20 Claims, 13 Drawing Sheets



U.S. PATENT DOCUMENTS

5,100,417 A	3/1992	Cerier et al.	7,309,337 B2	12/2007	Colleran
5,156,616 A	10/1992	Meadows et al.	7,322,978 B2	1/2008	West, Jr.
5,224,946 A	7/1993	Hayhurst et al.	7,500,983 B1	3/2009	Kaiser et al.
5,258,016 A	11/1993	DiPoto et al.	7,530,990 B2	5/2009	Perriello et al.
5,370,662 A	12/1994	Stone et al.	7,588,587 B2	9/2009	Barbieri et al.
5,417,533 A	5/1995	Lasner	7,611,521 B2	11/2009	Lubbers et al.
5,456,685 A	10/1995	Huebner	7,678,134 B2	3/2010	Schmieding et al.
5,472,452 A	12/1995	Trott	7,695,495 B2	4/2010	Dreyfuss
5,549,633 A	8/1996	Evans et al.	7,780,701 B1	8/2010	Meridew et al.
5,571,139 A	11/1996	Jenkins, Jr.	7,828,820 B2	11/2010	Stone et al.
5,573,548 A	11/1996	Nazre et al.	7,846,180 B2	12/2010	Cerier
5,584,836 A	12/1996	Ballintyn et al.	7,862,585 B2	1/2011	Li et al.
5,601,557 A	2/1997	Hayhurst	7,883,528 B2	2/2011	Grafton et al.
5,601,558 A	2/1997	Torrie et al.	7,883,529 B2	2/2011	Sinnott et al.
5,628,766 A	5/1997	Johnson	7,909,851 B2 *	3/2011	Stone et al. 606/232
5,643,320 A	7/1997	Lower et al.	8,029,536 B2	10/2011	Sorensen et al.
5,647,874 A	7/1997	Hayhurst	8,114,127 B2	2/2012	West, Jr.
D385,352 S	10/1997	Bales et al.	8,114,128 B2	2/2012	Cauldwell et al.
5,690,676 A	11/1997	DiPoto et al.	8,197,511 B2 *	6/2012	Miller et al. 606/232
5,709,708 A	1/1998	Thal	2002/0173822 A1	11/2002	Justin et al.
5,725,529 A	3/1998	Nicholson et al.	2003/0171778 A1	9/2003	Lizardi
5,733,307 A	3/1998	Dinsdale	2004/0093030 A1	5/2004	Cox et al.
5,814,070 A	9/1998	Borzzone et al.	2004/0106950 A1	6/2004	Grafton et al.
5,871,486 A	2/1999	Huebner et al.	2004/0153103 A1	8/2004	Schwartz et al.
5,891,146 A	4/1999	Simon et al.	2004/0167576 A1	8/2004	Pedlick et al.
5,891,168 A	4/1999	Thal	2004/0172062 A1	9/2004	Burkhart
5,893,880 A	4/1999	Egan et al.	2004/0254580 A1	12/2004	Boock et al.
5,911,721 A	6/1999	Nicholson et al.	2005/0075636 A1	4/2005	Gotzen
5,941,882 A	8/1999	Jammet et al.	2005/0222618 A1	10/2005	Dreyfuss et al.
5,951,560 A	9/1999	Simon et al.	2005/0222619 A1	10/2005	Dreyfuss et al.
5,957,953 A	9/1999	DiPoto et al.	2005/0245932 A1	11/2005	Fanton et al.
5,964,764 A	10/1999	West, Jr. et al.	2005/0267479 A1	12/2005	Morgan et al.
5,964,768 A	10/1999	Huebner	2006/0161159 A1	7/2006	Dreyfuss et al.
5,964,783 A	10/1999	Grafton et al.	2006/0189993 A1	8/2006	Stone
6,030,162 A	2/2000	Huebner	2006/0190042 A1	8/2006	Stone et al.
6,079,921 A	6/2000	Gauthier et al.	2006/0293675 A1	12/2006	Li et al.
6,096,060 A	8/2000	Fitts et al.	2007/0005069 A1	1/2007	Contiliano et al.
6,117,162 A	9/2000	Schmieding et al.	2007/0032792 A1	2/2007	Collin et al.
6,139,565 A	10/2000	Stone et al.	2007/0060922 A1	3/2007	Dreyfuss
6,214,031 B1	4/2001	Schmieding et al.	2007/0073299 A1	3/2007	Dreyfuss et al.
6,264,677 B1	7/2001	Simon et al.	2007/0142836 A1	6/2007	Schmieding et al.
6,299,615 B1	10/2001	Huebner	2007/0142837 A1	6/2007	Dreyfuss
6,436,124 B1	8/2002	Anderson et al.	2007/0173845 A1	7/2007	Kim
6,468,277 B1	10/2002	Justin et al.	2007/0185494 A1	8/2007	Reese
6,511,499 B2	1/2003	Schmieding et al.	2007/0219557 A1	9/2007	Bourque et al.
6,517,564 B1	2/2003	Grafton et al.	2007/0219558 A1	9/2007	Deutsch
6,517,578 B2	2/2003	Hein	2008/0009904 A1	1/2008	Bourque et al.
6,569,188 B2	5/2003	Grafton et al.	2008/0167660 A1	7/2008	Moreau et al.
6,610,080 B2	8/2003	Morgan	2008/0306510 A1	12/2008	Stchur
6,616,665 B2	9/2003	Grafton et al.	2009/0082807 A1	3/2009	Miller et al.
6,635,074 B2	10/2003	Bartlett	2009/0234387 A1	9/2009	Miller et al.
6,641,597 B2	11/2003	Dreyfuss et al.	2010/0094355 A1	4/2010	Trenhaile
6,648,892 B2	11/2003	Martello	2010/0100127 A1	4/2010	Trenhaile
6,652,563 B2	11/2003	Dreyfuss	2010/0152773 A1	6/2010	Lunn et al.
6,685,728 B2	2/2004	Sinnott et al.	2011/0054526 A1	3/2011	Stone et al.
6,726,707 B2	4/2004	Pedlick et al.	2011/0224727 A1	9/2011	Housman et al.
6,730,092 B2	5/2004	Songer			
6,773,436 B2	8/2004	Donnelly et al.			
6,840,953 B2	1/2005	Martinek			
6,887,259 B2	5/2005	Lizardi			
6,916,333 B2	7/2005	Schmieding et al.			
6,923,824 B2	8/2005	Morgan et al.			
7,081,126 B2	7/2006	McDevitt et al.			
7,090,675 B2	8/2006	Songer			
7,163,540 B2	1/2007	Martello			
7,189,251 B2	3/2007	Kay			
7,195,634 B2	3/2007	Schmieding et al.			
7,217,279 B2	5/2007	Reese			
7,226,469 B2	6/2007	Benavitz et al.			
7,232,455 B2	6/2007	Pedlick et al.			

FOREIGN PATENT DOCUMENTS

EP	1 260 182	A3	11/2002
EP	1 300 115	A1	4/2003
EP	1 486 171	A1	12/2004
EP	1 530 951	A2	5/2005
EP	1 762 187	A1	3/2007
EP	1 797 827	A1	6/2007
FR	2 254 298		11/1975
FR	02 588 332		4/1987
JP	2003010198	A1	1/2003
SU	01034734		8/1983

* cited by examiner

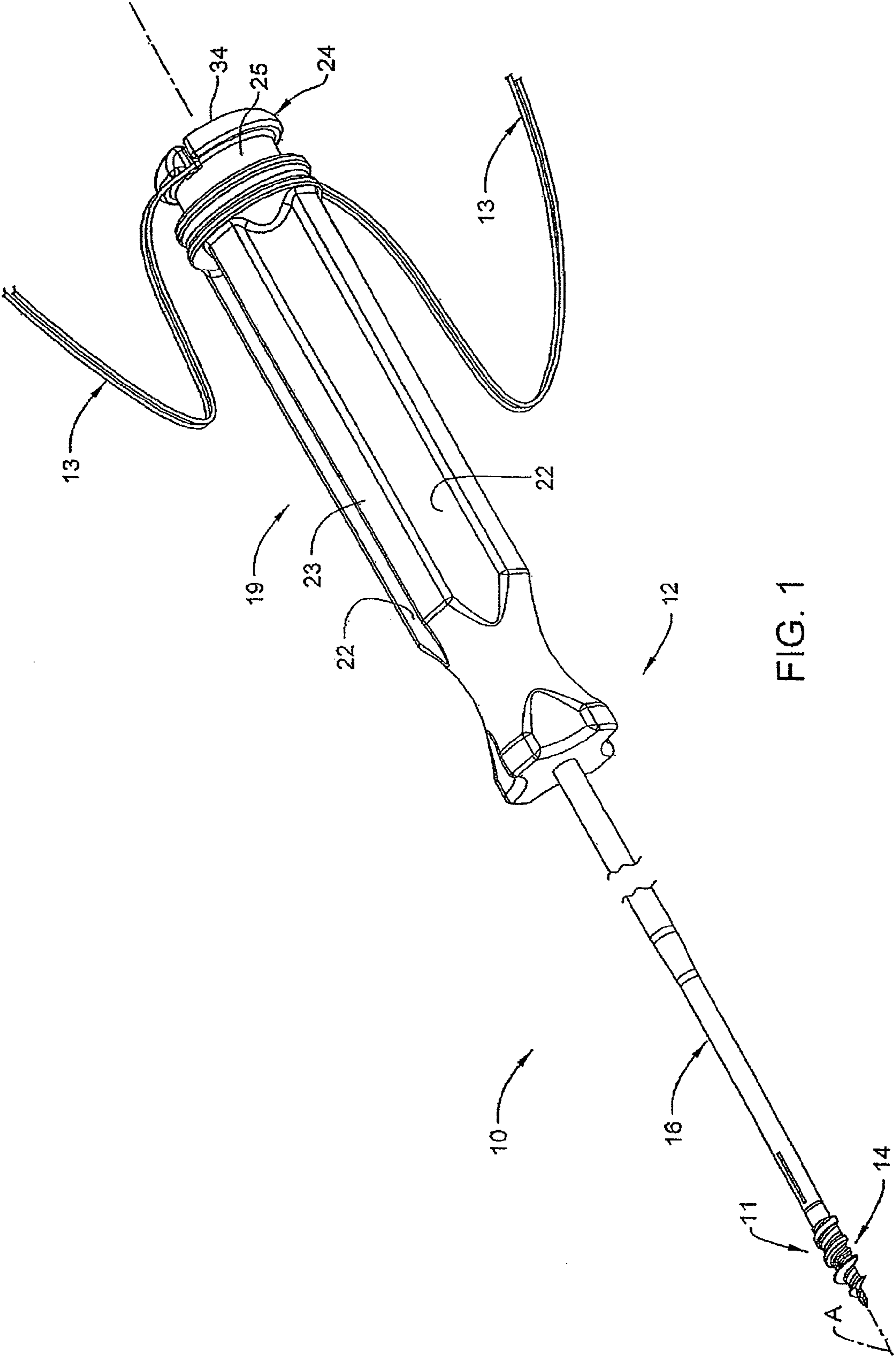
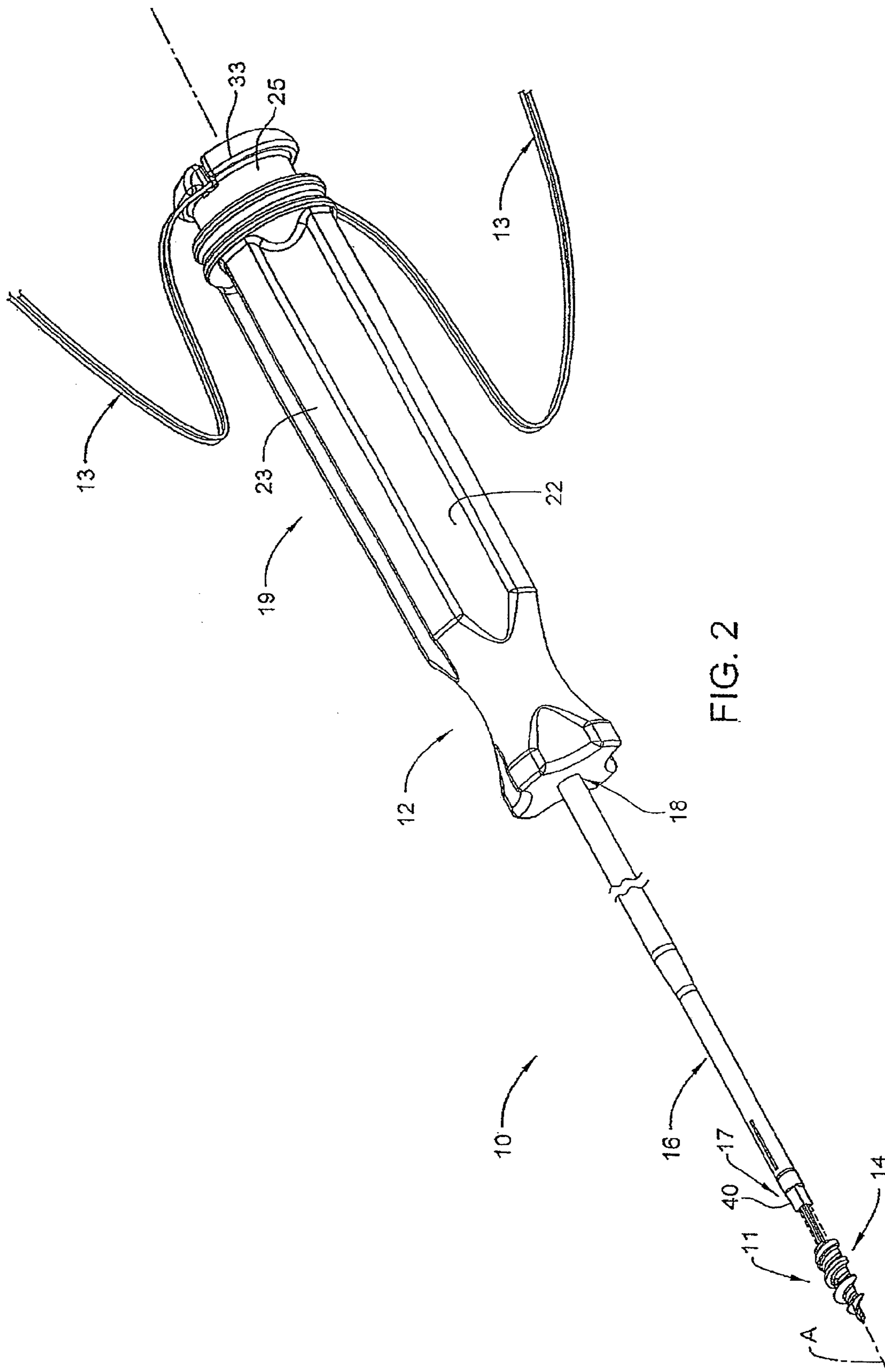


FIG. 1



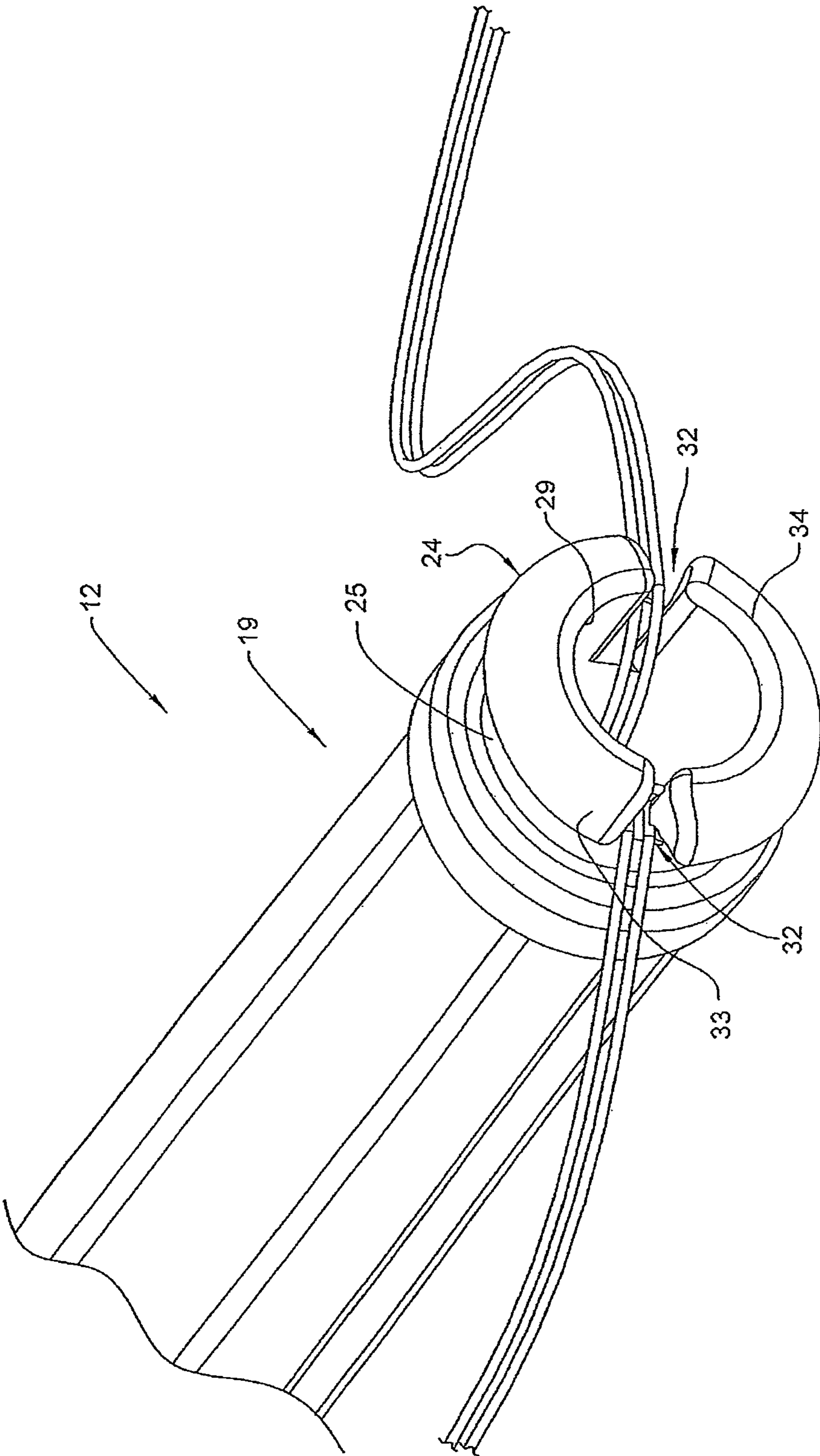


FIG. 3

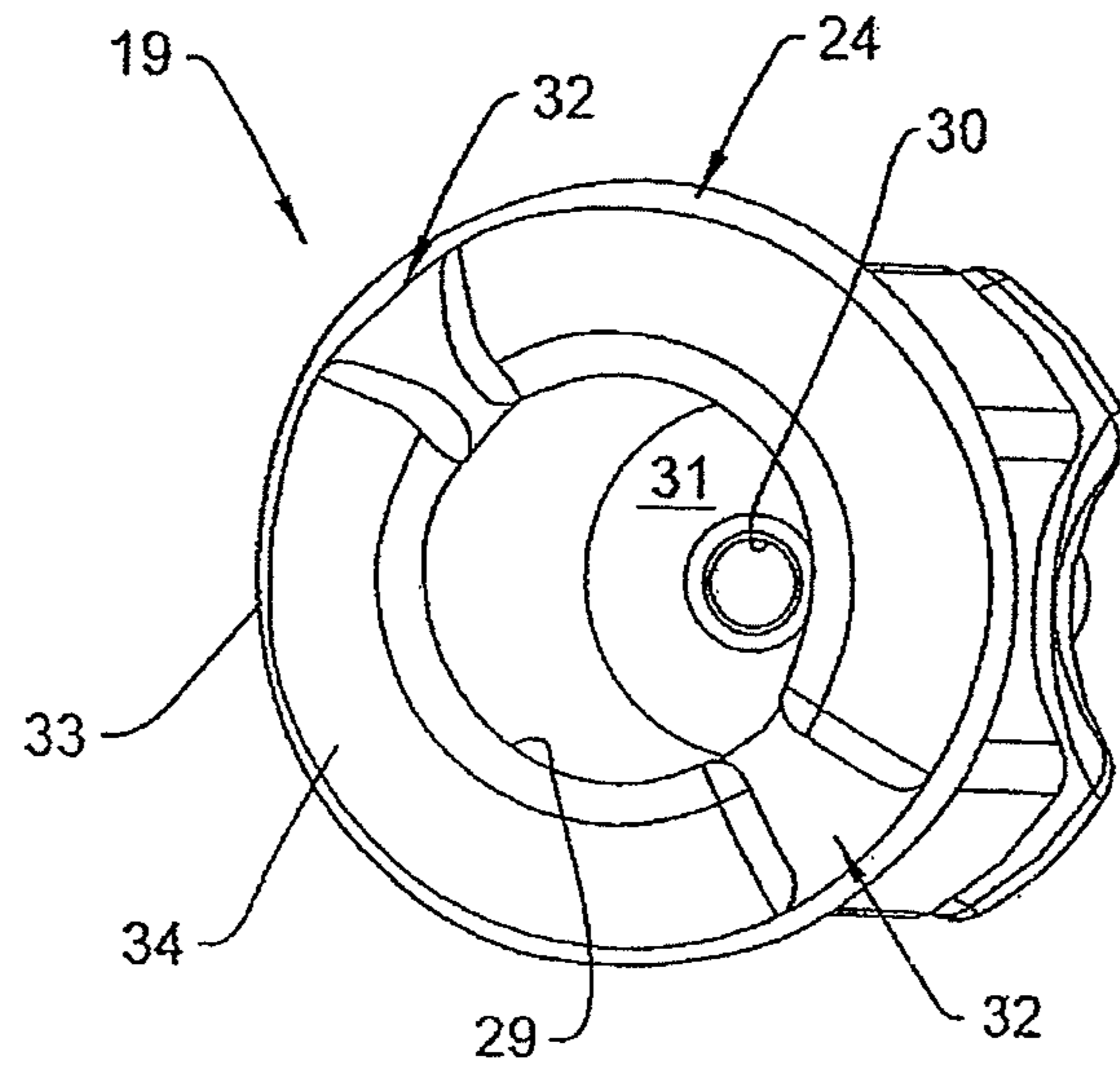


FIG. 4

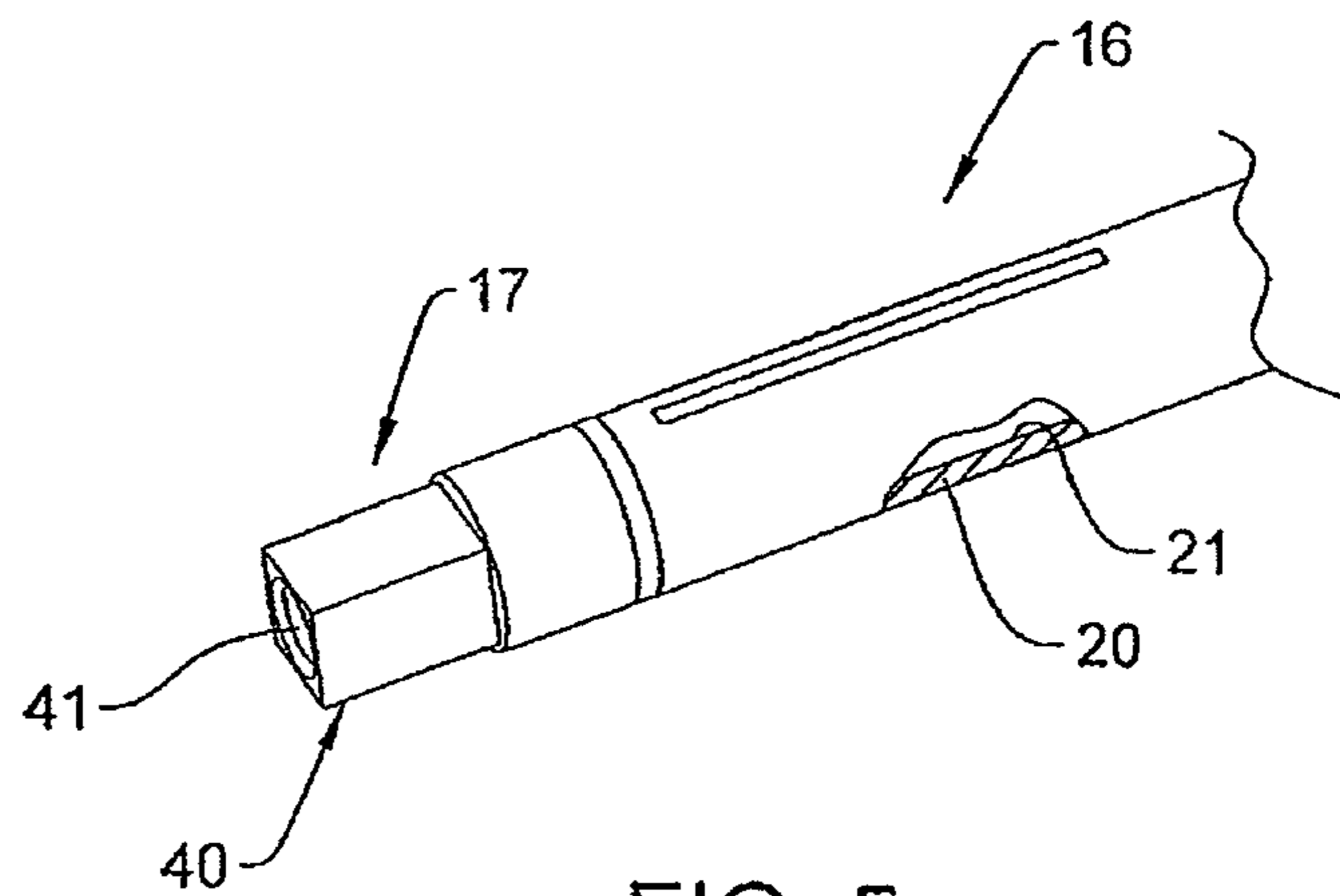


FIG. 5

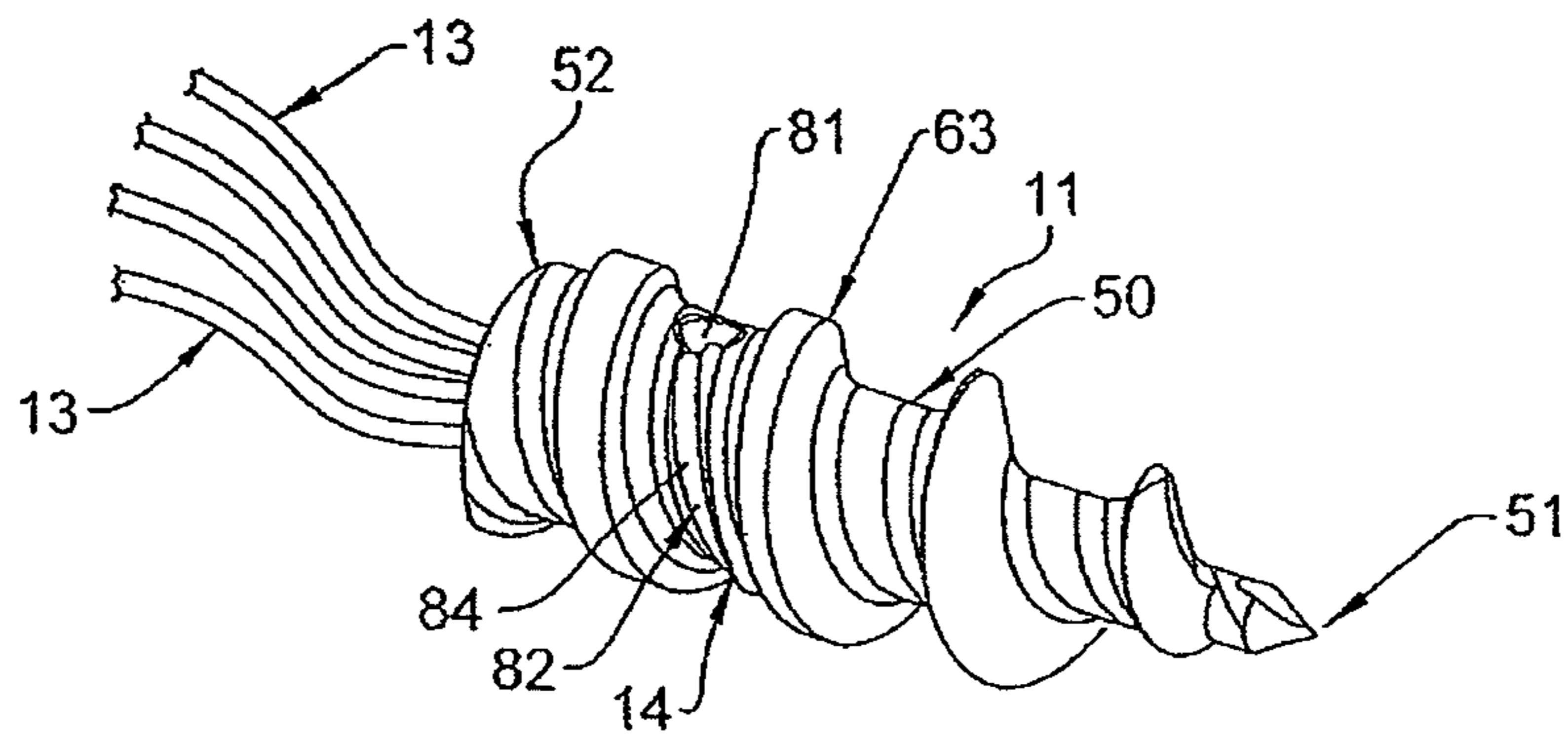


FIG. 6

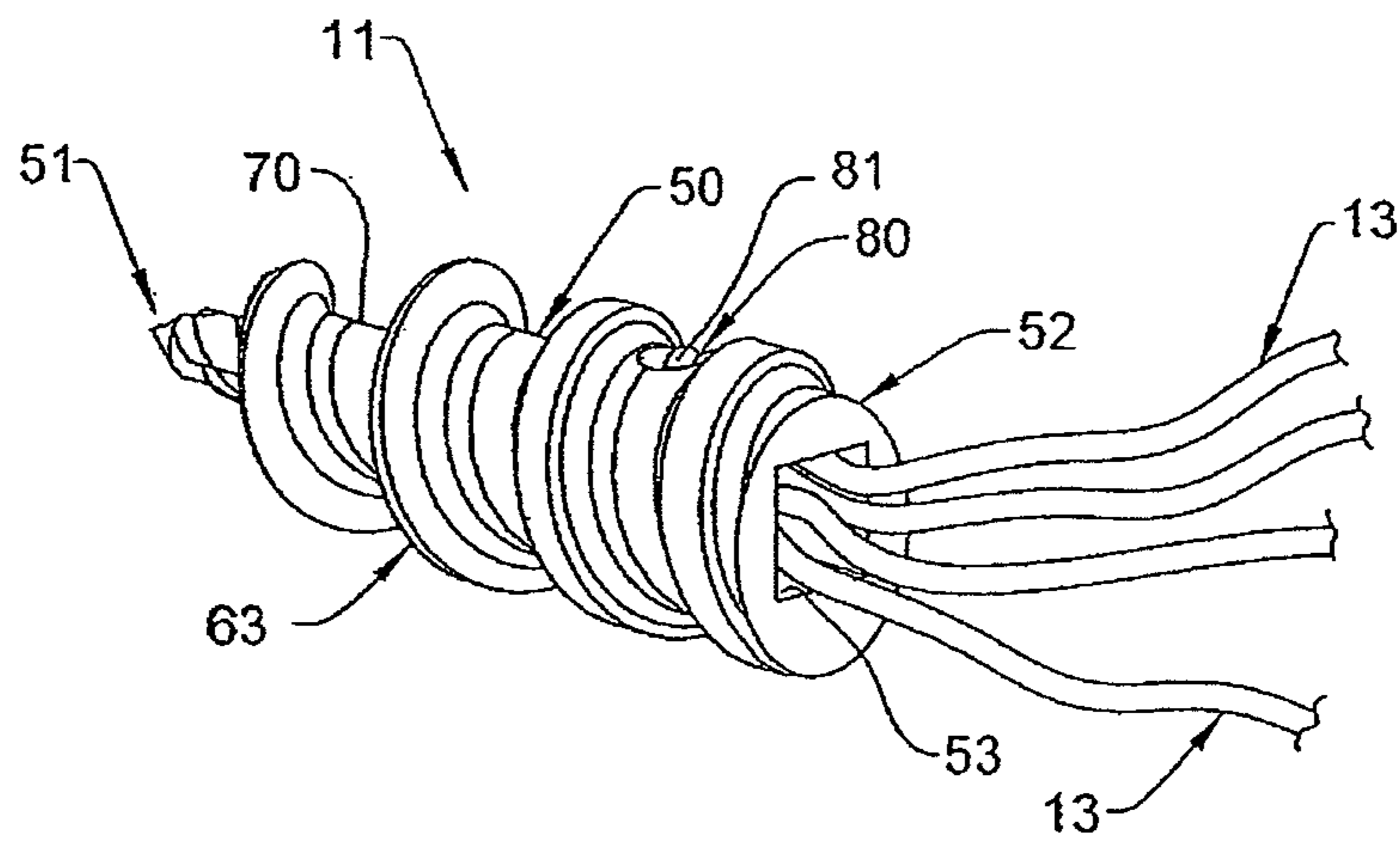


FIG. 7

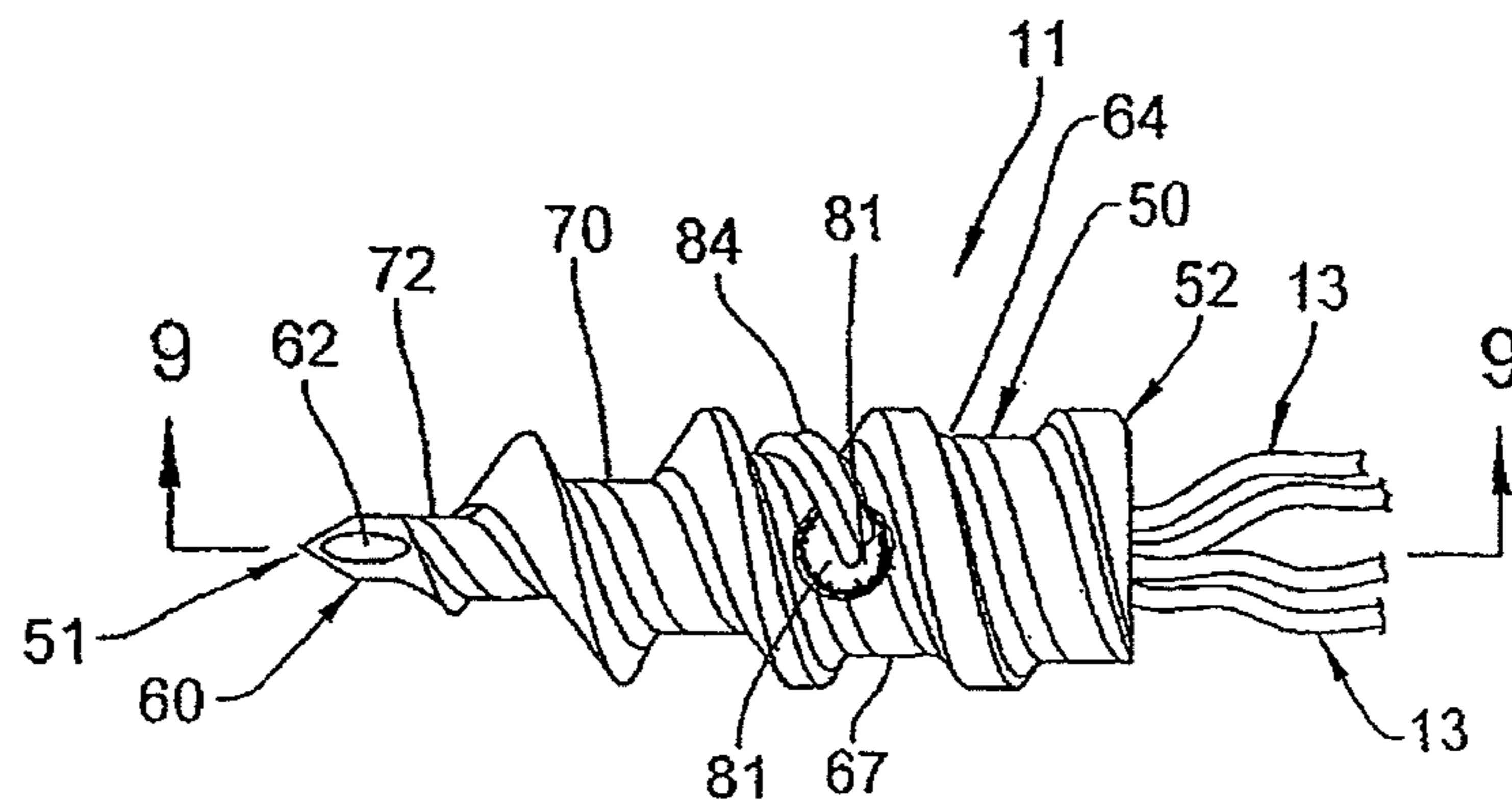


FIG. 8

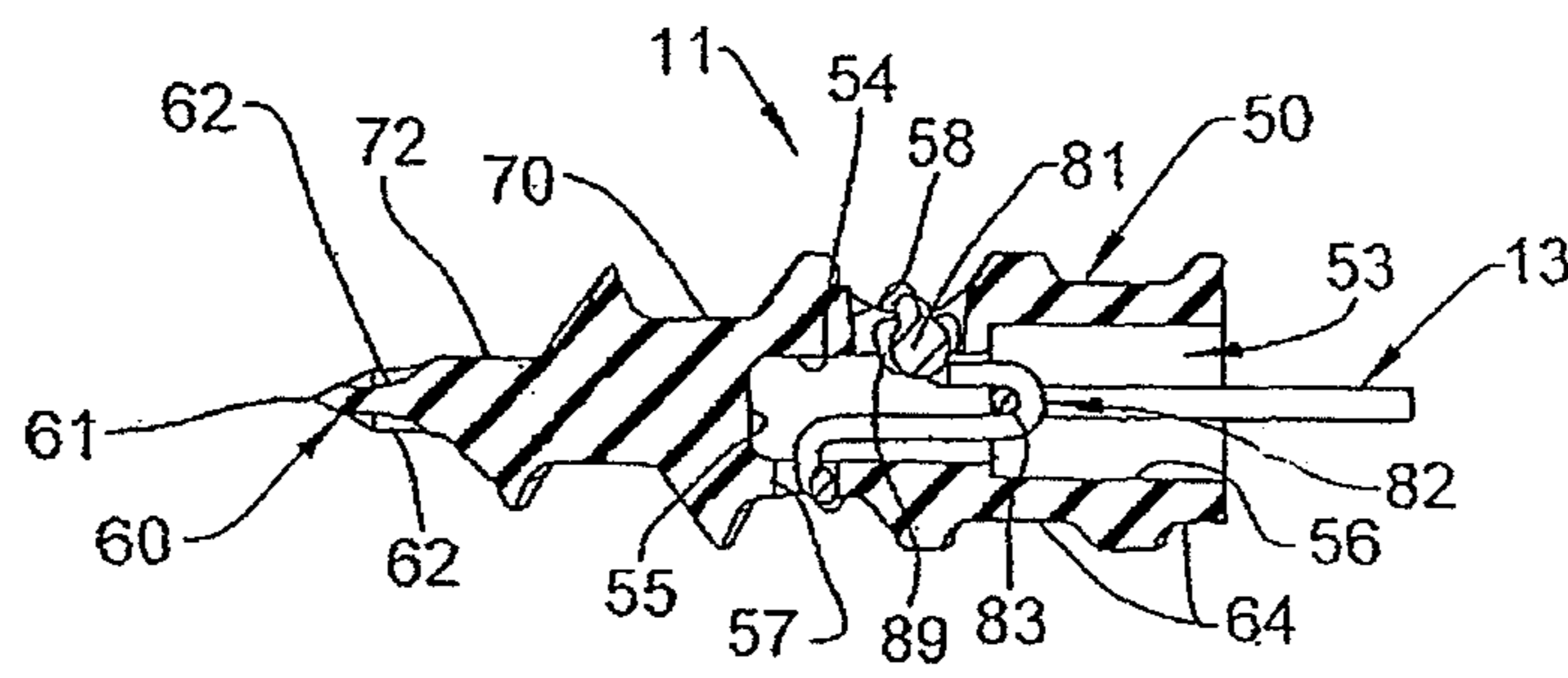


FIG. 9

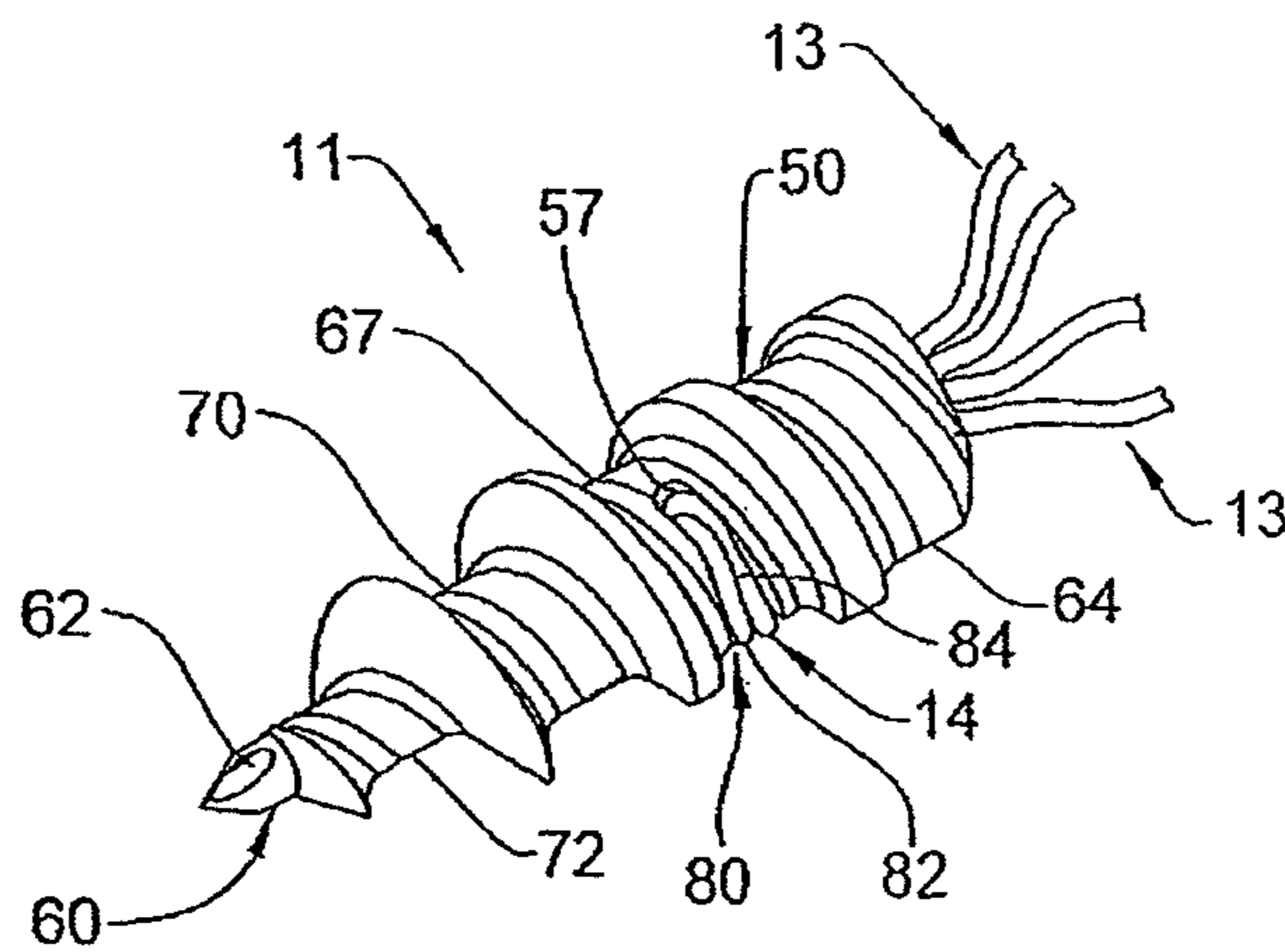


FIG. 10

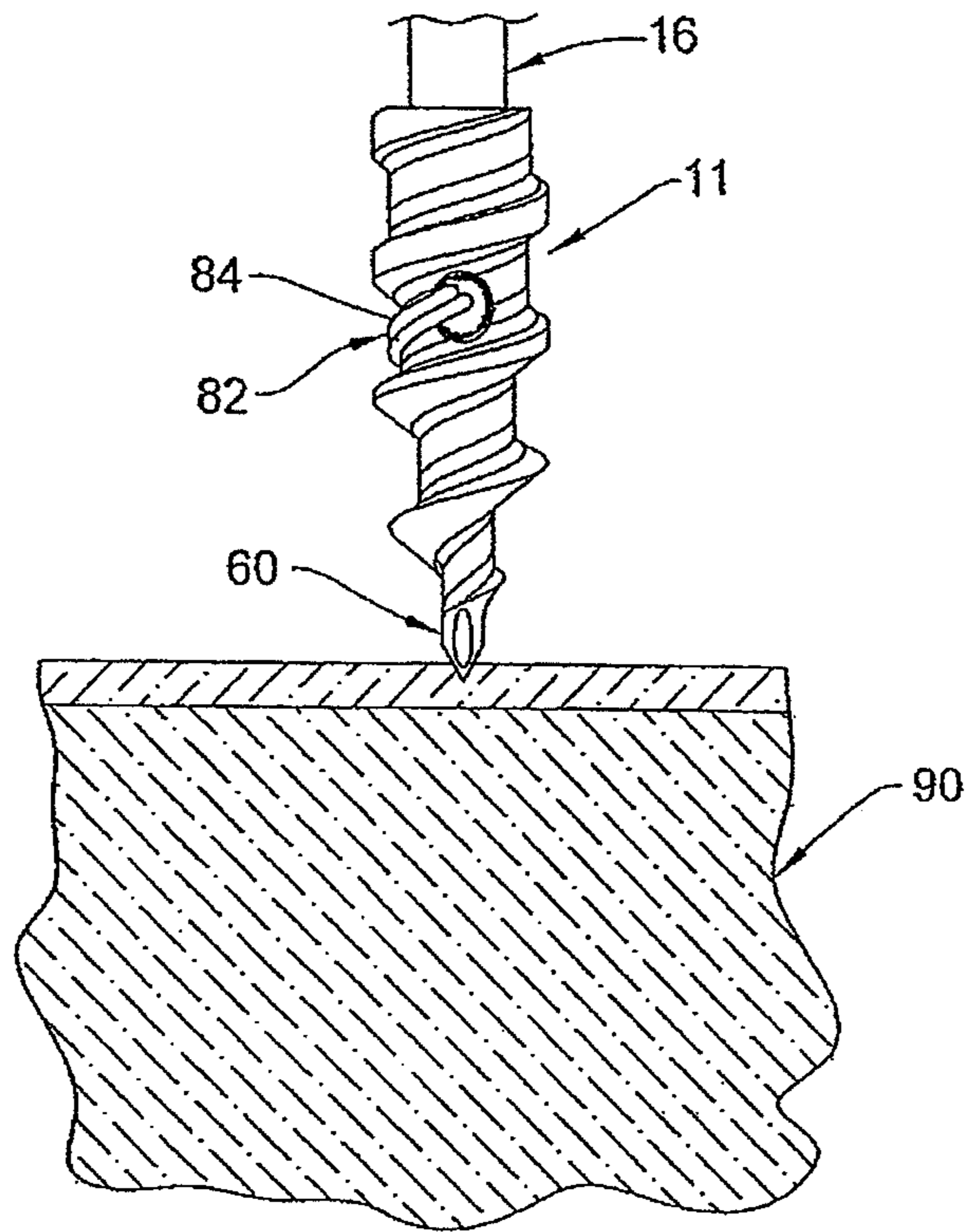


FIG. 11

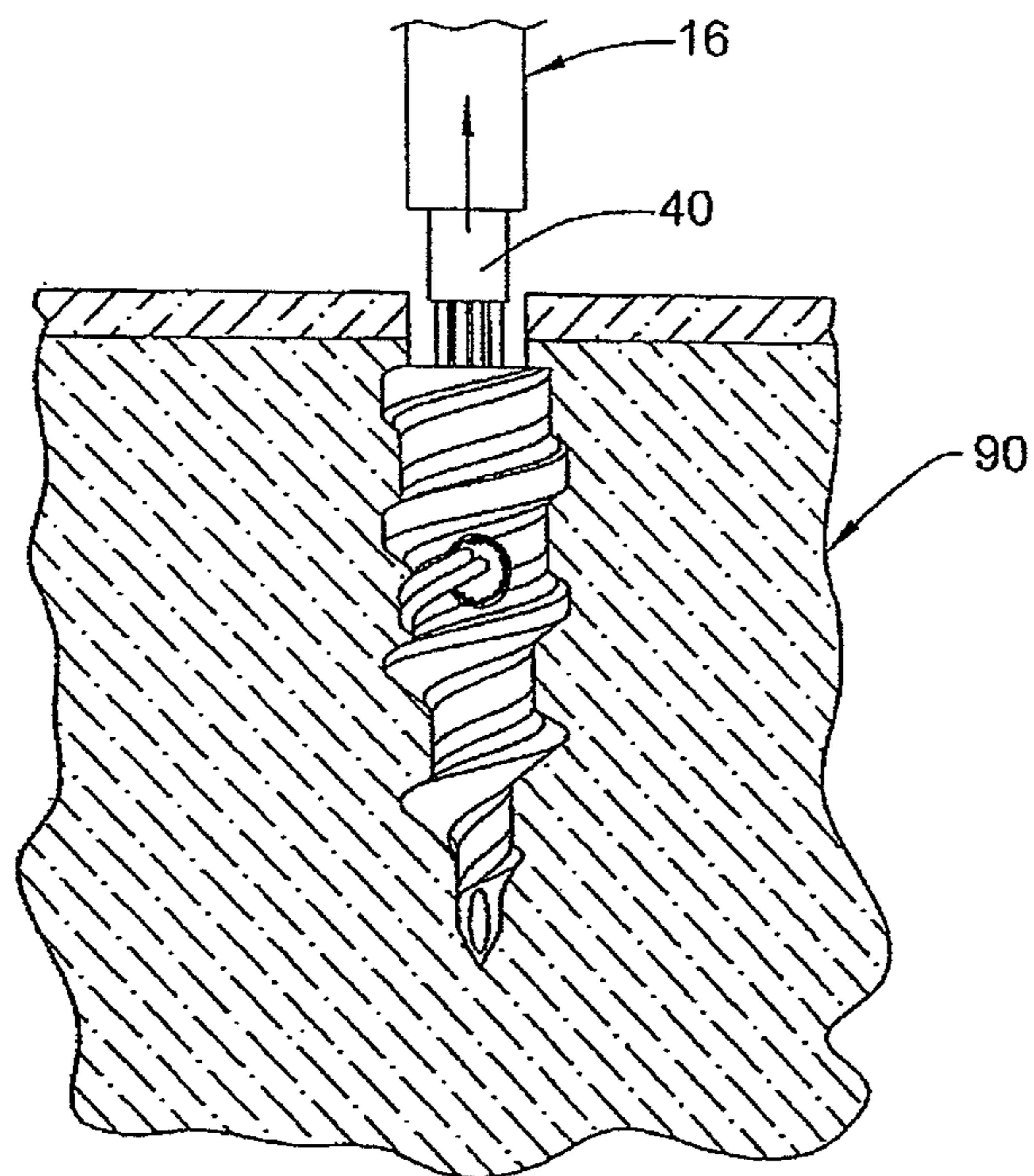


FIG. 12

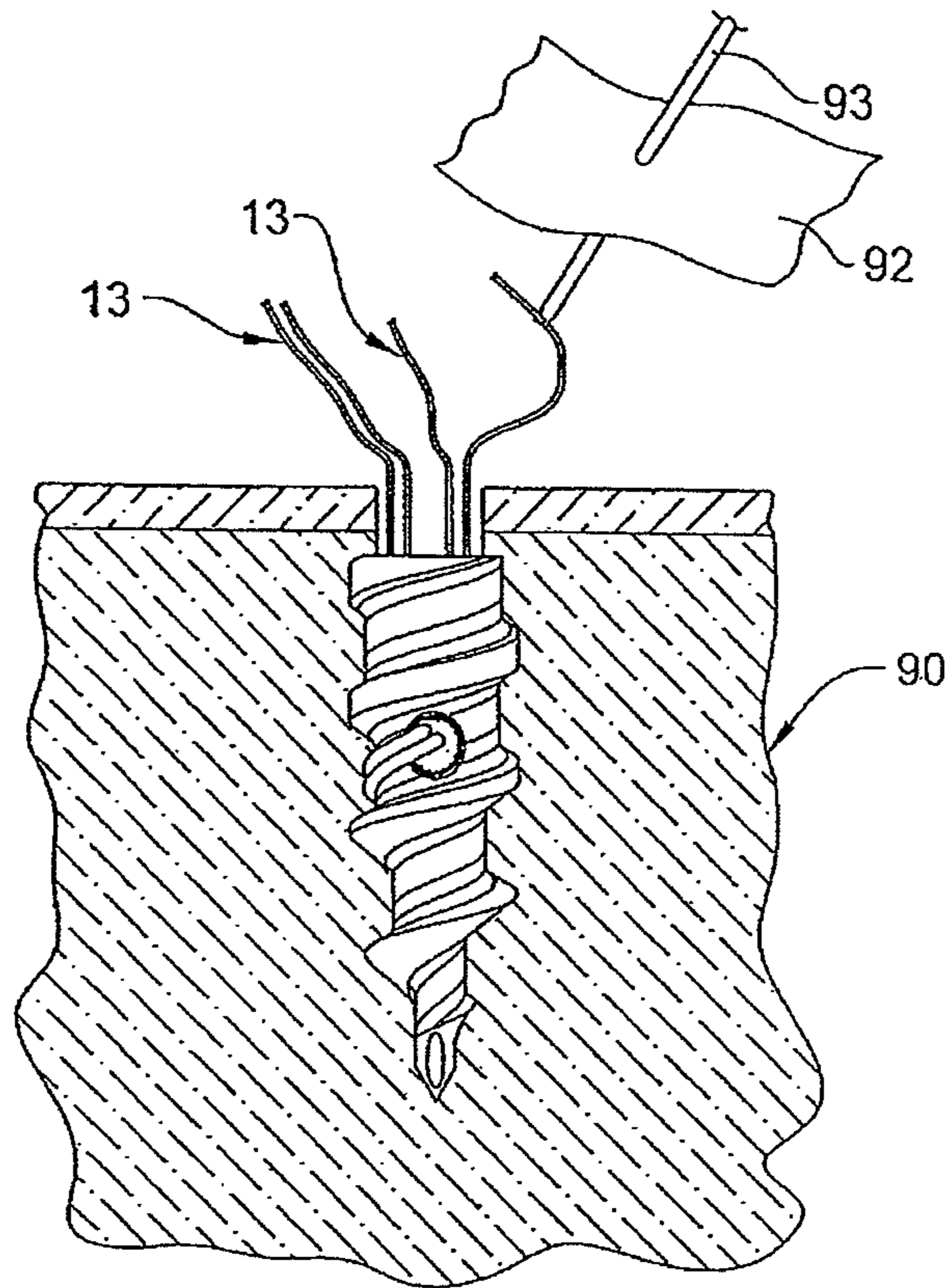


FIG. 13

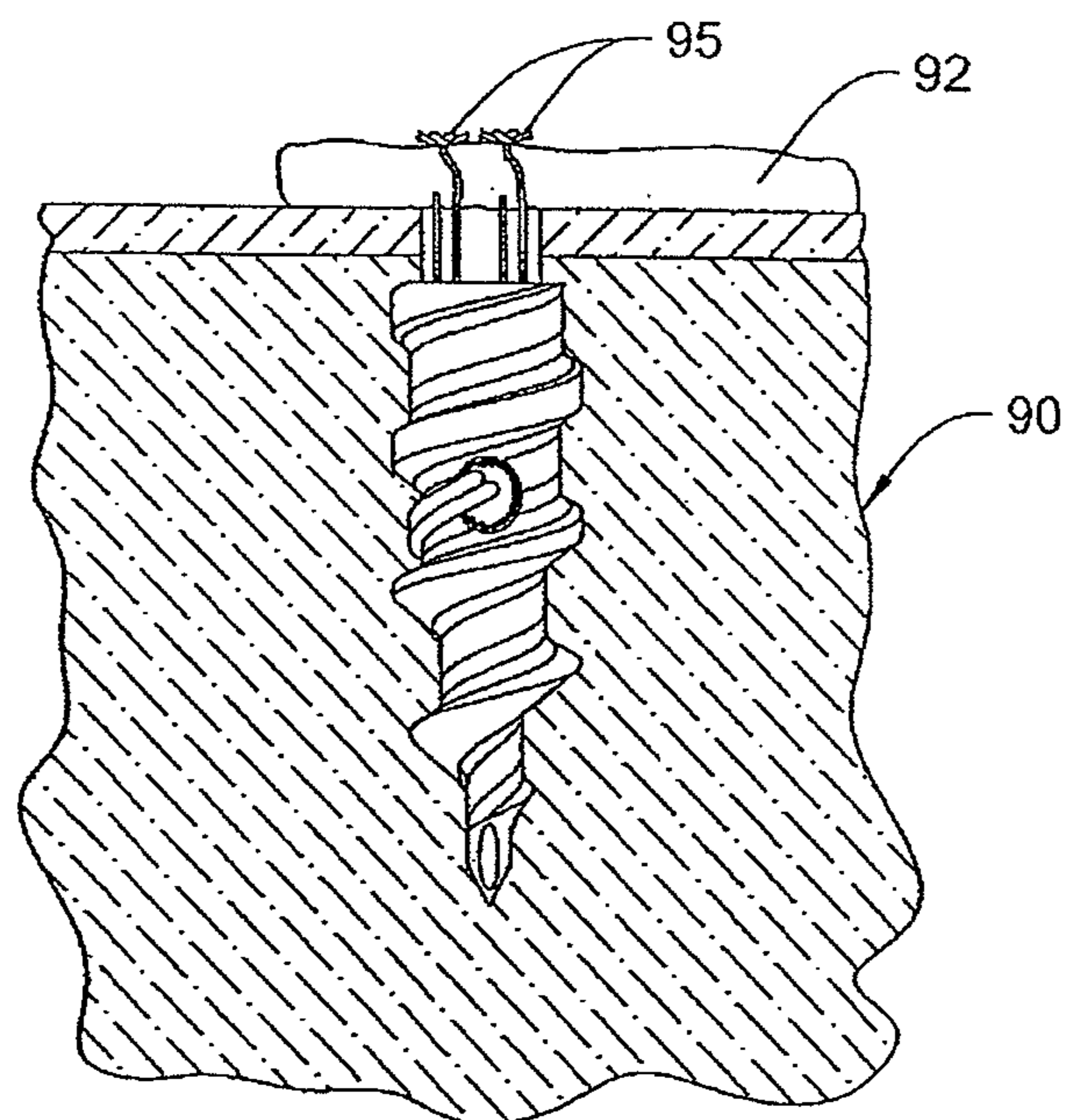


FIG. 14

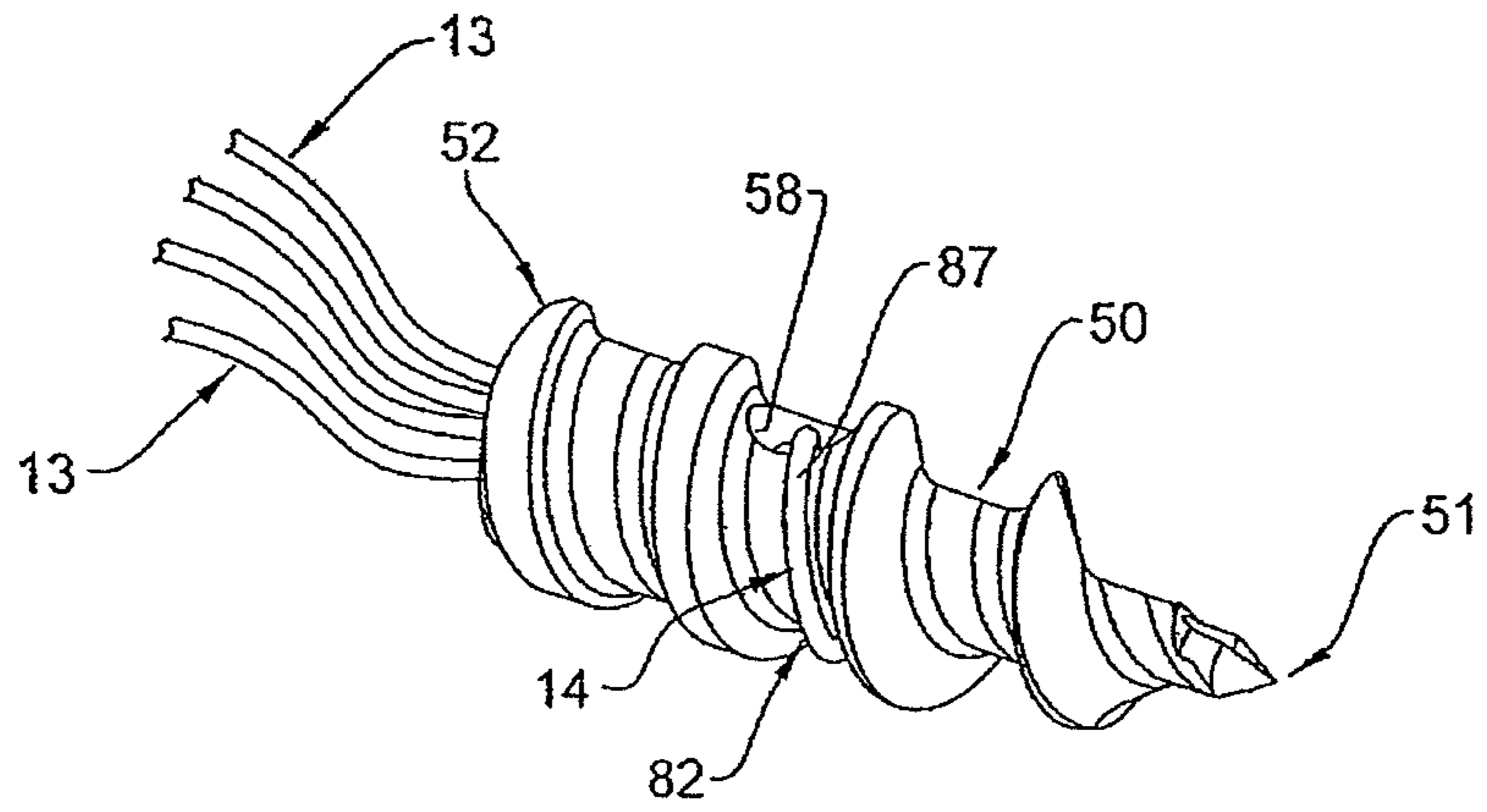


FIG. 15

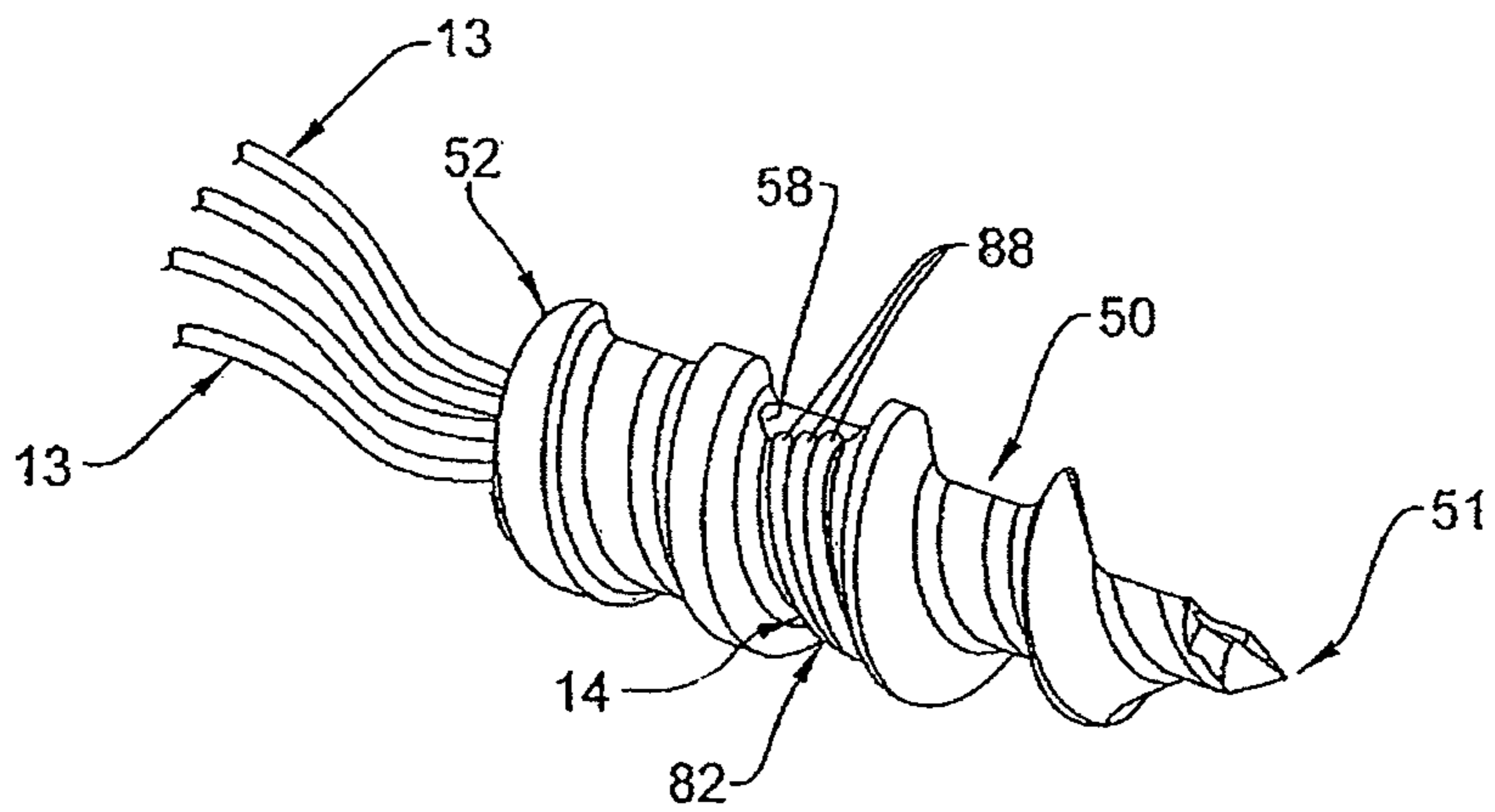


FIG. 16

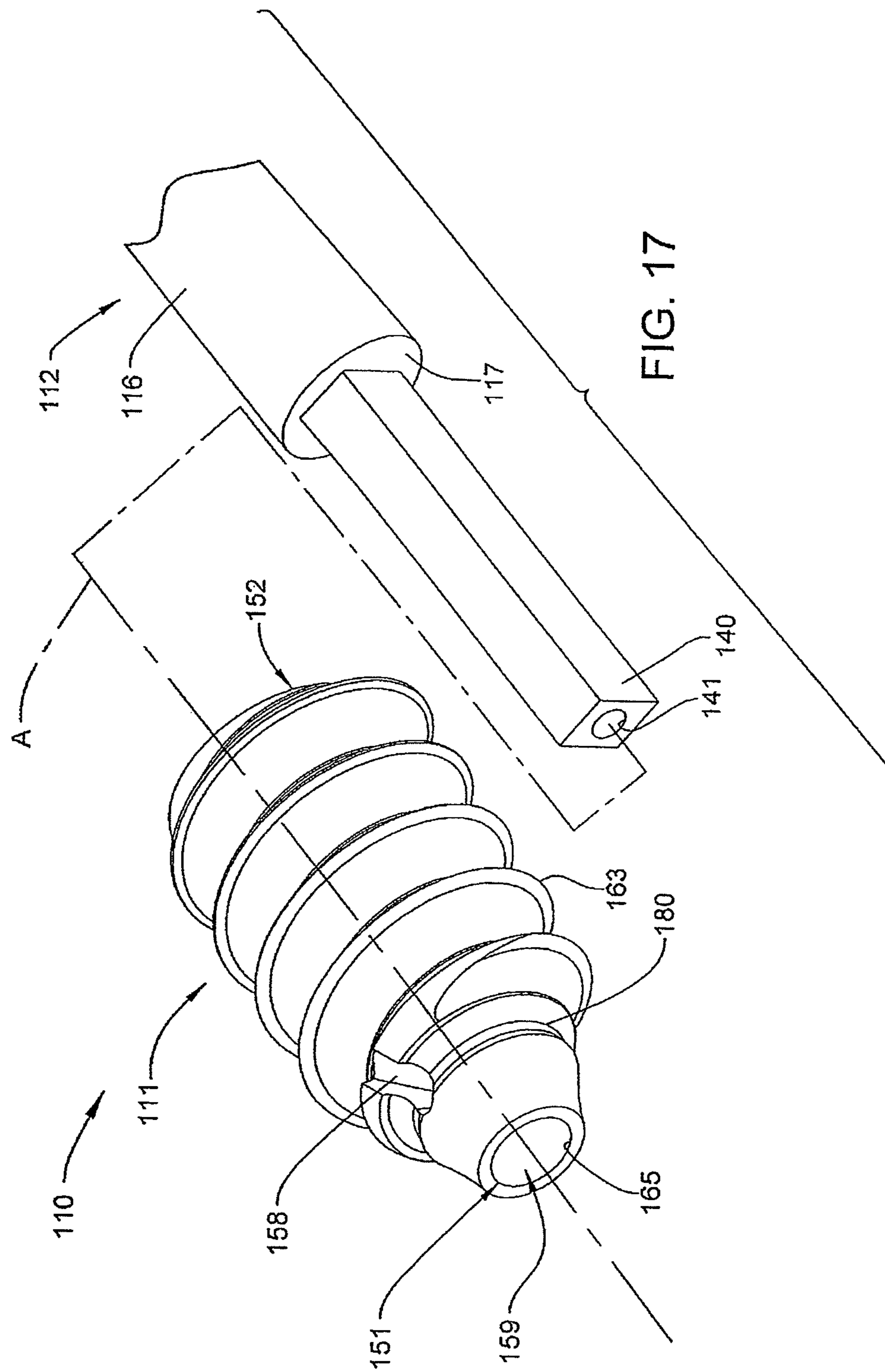


FIG. 17

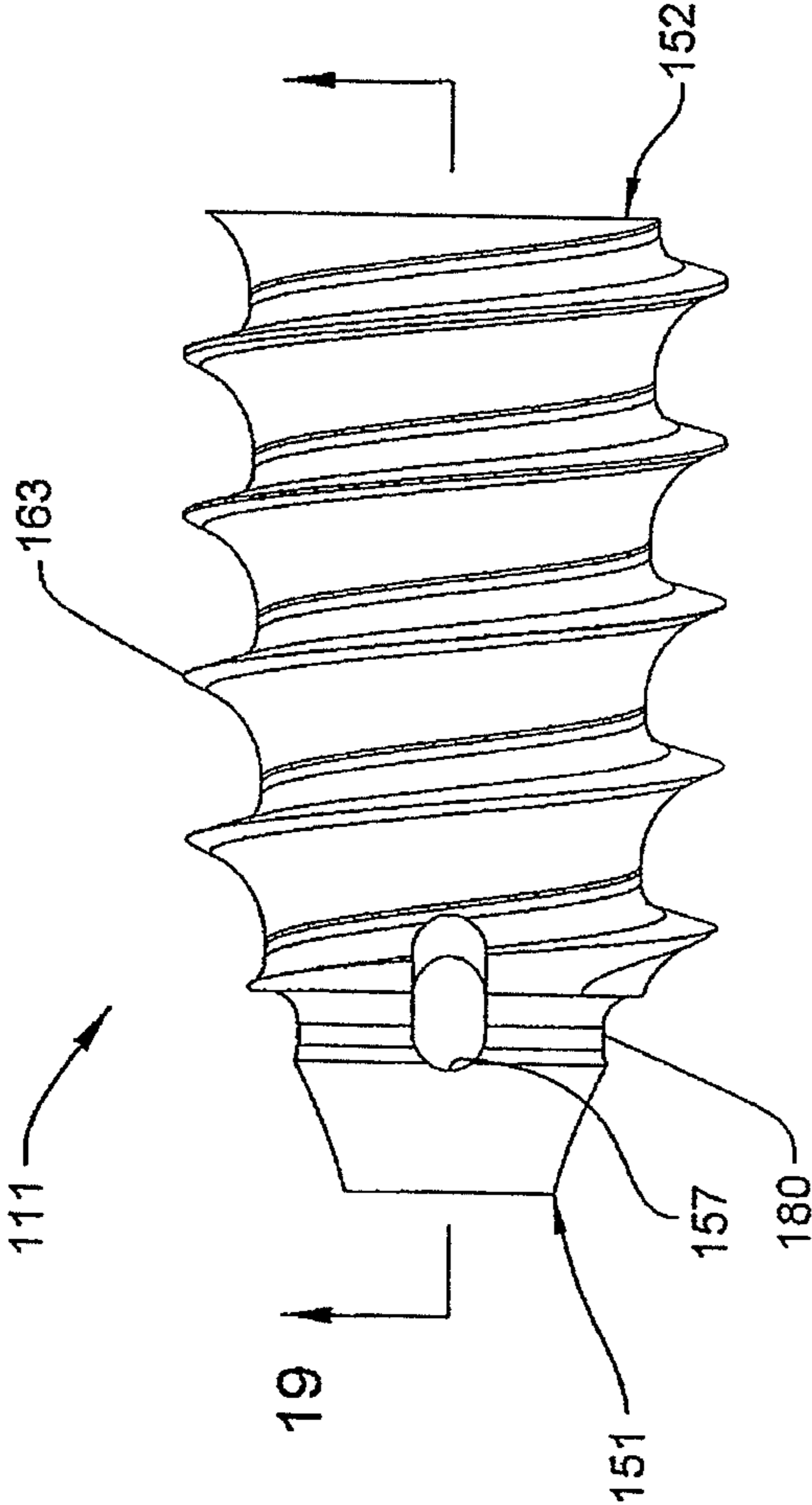


FIG. 18

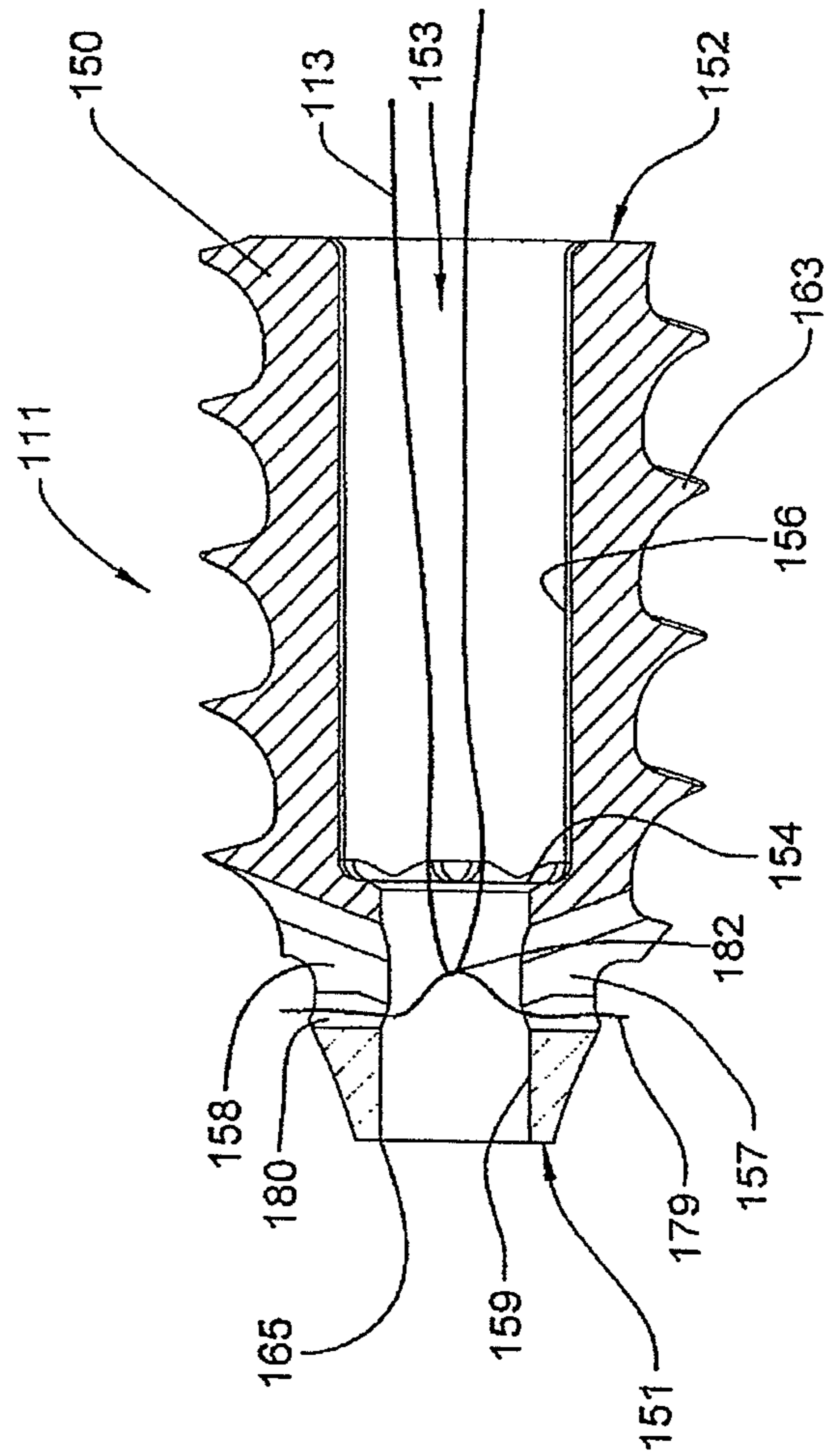


FIG. 19

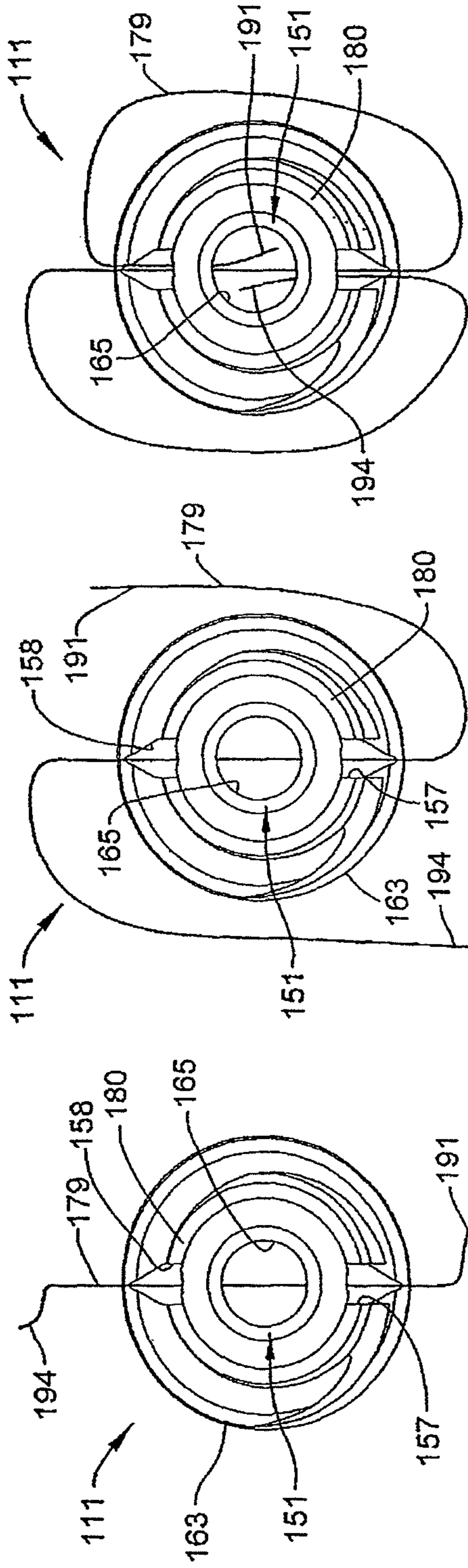


FIG. 20A

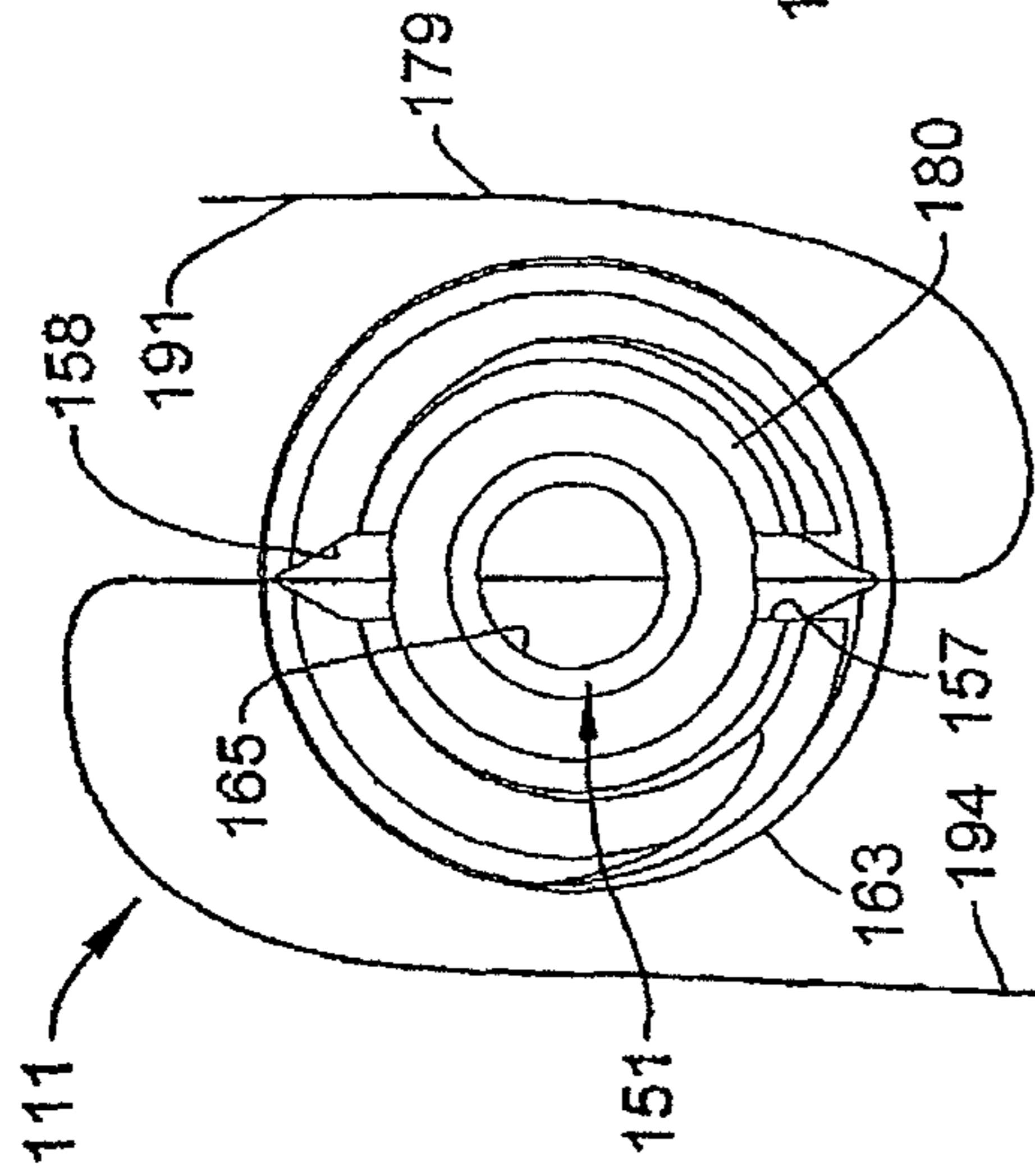


FIG. 20B

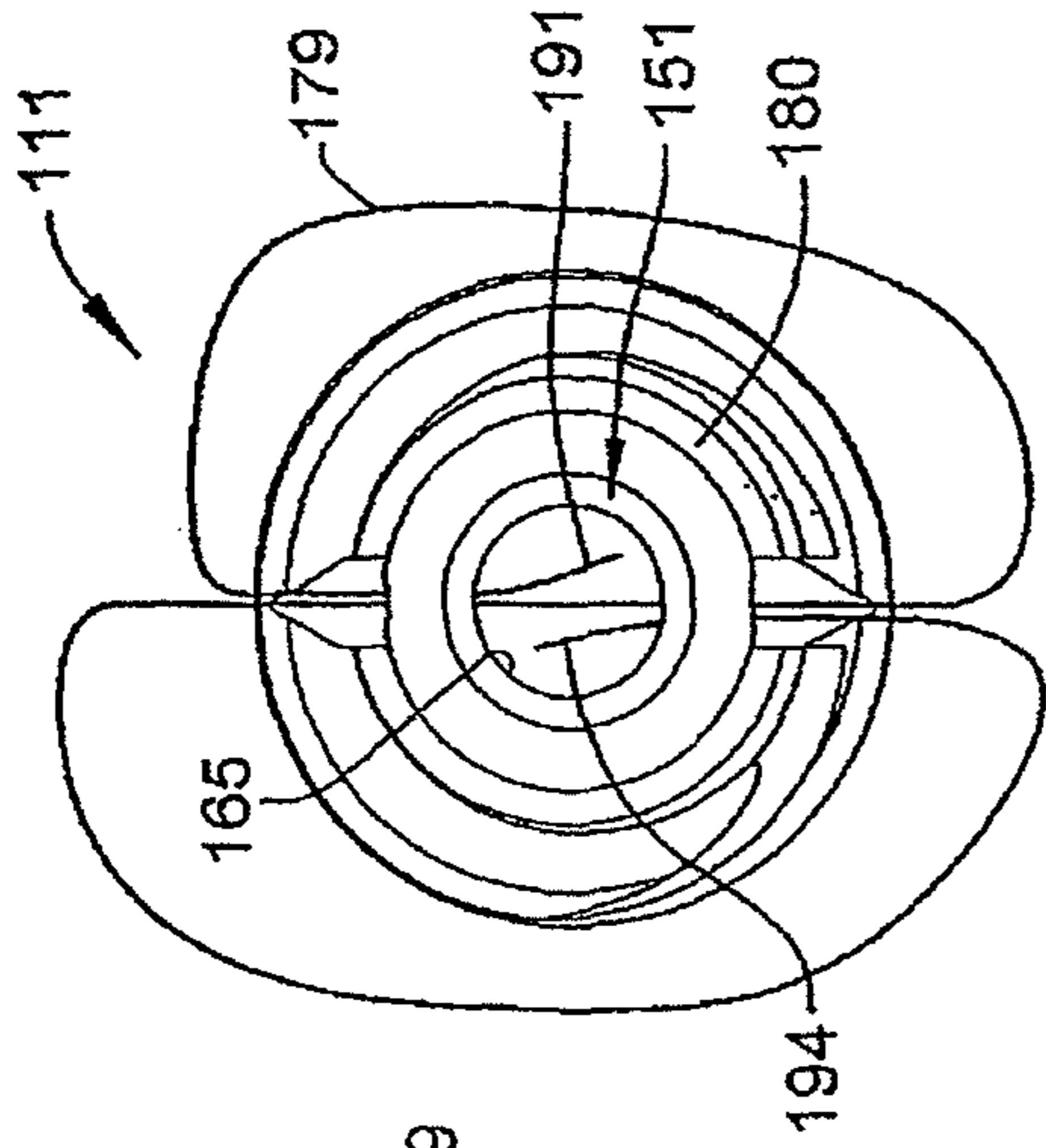


FIG. 20C

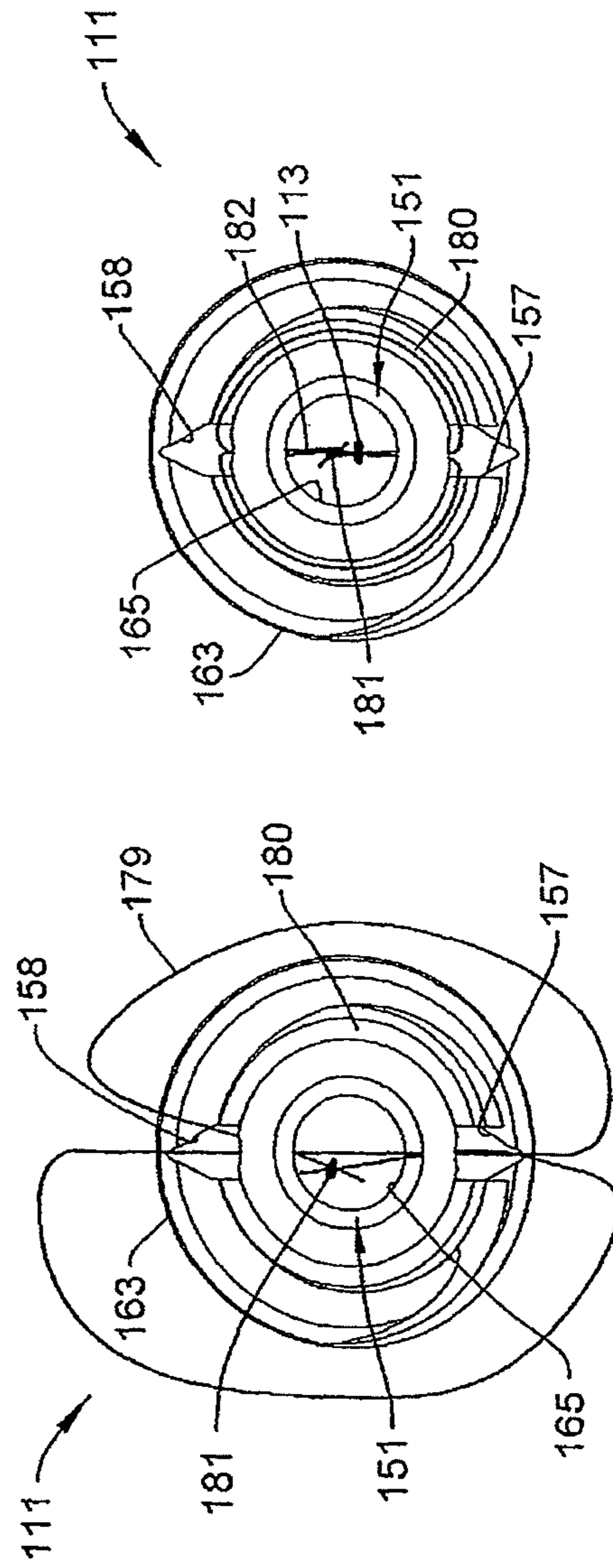


FIG. 20D

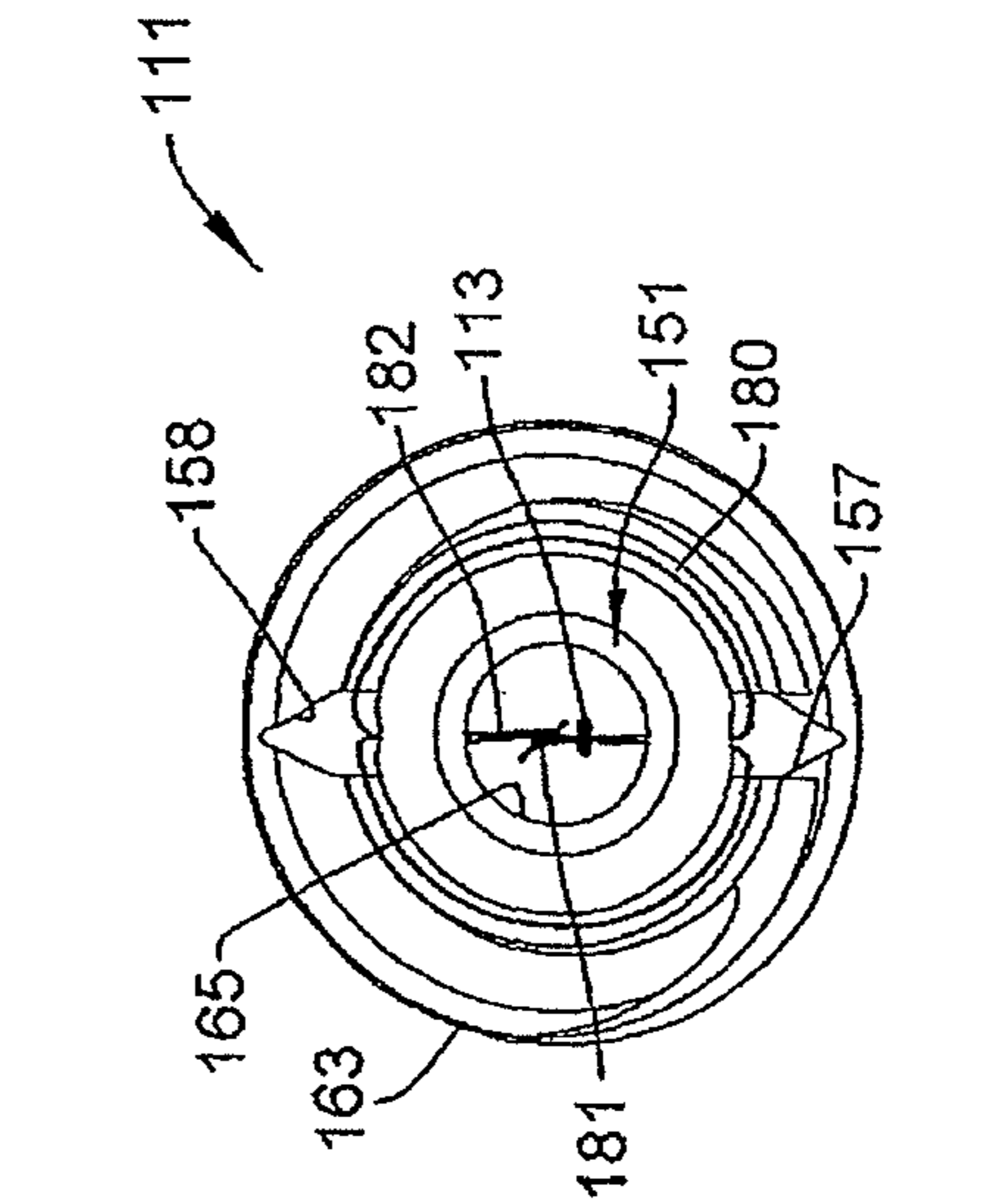


FIG. 20E

1

SUTURE ANCHOR HAVING A SUTURE ENGAGING STRUCTURE AND INSERTER ARRANGEMENT

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 12/380,891, filed Mar. 4, 2009 and issued on Jun. 12, 2012 as U.S. Pat. No. 8,197,511, which is a continuation-in-part application of co-pending U.S. patent application Ser. No. 11/903,738, filed Sep. 24, 2007.

FIELD OF THE INVENTION

This invention relates to a suture anchor and inserter arrangement for use in fixing surgical suture to hard tissue.

BACKGROUND OF THE INVENTION

During some injuries, soft tissue, such as tendons or ligaments, can tear away from hard tissue, such as bone. Accordingly, it becomes necessary to reattach the soft tissue to the bone in order to facilitate the healing process. Various types of devices are used to reattach tissue, such as screws, staples and suture anchors. The instant invention relates to this latter type of attachment device.

Suture anchors may be inserted into a preformed hole made in the hard tissue, while other anchors are self-tapping. The anchors typically include an eyelet or other structure through which lengths of repair suture or working suture are threaded, which working suture is inserted simultaneously with the anchor into the hard tissue. In this regard, in some anchors, the eyelet is disposed exteriorly on the anchor, for example adjacent to or even forming part of a drive head located on the proximal end of the anchor, and in other anchors is formed interiorly within a bore defined inside the anchor. The eyelet may be formed from suture material, as disclosed in U.S. Pat. No. 6,641,597, and in other instances is formed as a rigid and integral component of the anchor body, as disclosed in U.S. Pat. No. 5,584,836. A further suture-engaging structure is disclosed in U.S. Patent Publication No. 2005/0222618, wherein the anchor incorporates a rigid pin disposed transversely across an interior bore defined in the anchor. In this variation, the working sutures are inserted into the proximal end of the anchor bore and looped over the pin to secure the suture to the anchor.

It has also been discovered that increasing the biological integration of the suture anchor with the bone in which the anchor is implanted can reduce rejection potential and speed healing. One embodiment of a suture anchor according to the invention is hollow and includes a continuous through-bore, so that the tip or distal end of the anchor, which is embedded in the bone tissue, is open, allowing the permeation/migration of blood, bone marrow, and their components (including platelets and mesenchymal stem cells) into the repair site. The anchor is further formed of a bio-absorbable material, which also enhances healing and integration of the suture and anchor into the bone tissue.

An inserter device or driver may be utilized in conjunction with the anchor to install or drive same into hard tissue and may carry working sutures thereon. For the purpose of providing pull-out resistance once the anchor is installed, some anchors are exteriorly threaded, while others are ribbed or barbed to provide appropriate pull-out resistance.

The suture anchor according to the present invention includes an anchor body having a distal end configured for

2

insertion into hard tissue and a proximal end spaced from the distal end. The anchor body carries thereon a suture engagement structure which cooperates with working suture to attach same to the suture anchor. The suture-engaging structure may, according to one embodiment, be defined by suture material, and may be formed as a continuous loop of suture material having a portion thereof located interiorly of the anchor, such that the working suture is looped over this interior portion of the suture loop to engage the working suture with the anchor.

The suture anchor according to the invention in one embodiment is configured for cooperation with an inserter or driver device. The inserter device includes a handle for manipulating the device and an inserter shaft which supports the suture anchor at the distal end thereof. The inserter device carries working sutures, which working sutures are engaged with the anchor via the suture engagement structure as discussed above, and then extend proximally either interiorly or exteriorly of the inserter device.

One possible use of the arrangement is in arthroscopic shoulder surgery, wherein the dislocation of soft tissue relative to the bone is a fairly common injury. However, this arrangement may also be utilized for the repair of small joints, such as the elbow, wrist, ankle, hand or foot. The arrangement may additionally be used to reattach small ligaments in the knee.

Other objects and purposes of the invention will be apparent to persons familiar with arrangements of this general type upon reading the following specification and inspecting the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a fragmentary perspective view of the suture anchor and inserter arrangement according to the invention.

FIG. 2 is a fragmentary, partially-exploded perspective view of the arrangement of FIG. 1.

FIG. 3 is an enlarged, fragmentary perspective view of the proximal end of the inserter device.

FIG. 4 is an enlarged perspective end view of the proximal end of the inserter device.

FIG. 5 is an enlarged, fragmentary perspective view of the distal end of the inserter device.

FIG. 6 is an enlarged perspective side view of the suture anchor with working sutures attached thereto.

FIG. 7 is an enlarged perspective side view of the suture anchor rotated approximately 180° from the position shown in FIG. 6, showing the proximal end of the suture anchor.

FIG. 8 is an enlarged plan view of the suture anchor.

FIG. 9 is a cross-sectional view of the suture anchor, taken generally along line 9-9 in FIG. 8.

FIG. 10 is an enlarged perspective side view of the suture anchor.

FIG. 11 is a fragmentary view illustrating the suture anchor being installed within a bone using the inserter device.

FIG. 12 is a fragmentary view illustrating the inserter device being pulled away from the suture anchor.

FIG. 13 is fragmentary view illustrating the attachment of the working sutures to soft tissue.

FIG. 14 is a fragmentary view illustrating the soft tissue fully attached to the bone.

FIG. 15 is an enlarged perspective side view of the suture anchor with an alternative suture engagement structure.

FIG. 16 is an enlarged perspective side view of the suture anchor with yet another alternative suture engagement structure.

3

FIG. 17 is a fragmentary, partially exploded perspective view of a suture anchor and inserter arrangement according to a further embodiment of the invention.

FIG. 18 is a plan view of the suture anchor of FIG. 17.

FIG. 19 is a cross-sectional view of the suture anchor, taken generally along line 19-19 of FIG. 18.

FIGS. 20A-20E are distal end views of the suture anchor of FIGS. 17-19, showing assembly of the soft eyelet to the anchor body.

Certain terminology will be used in the following description for convenience in reference only, and will not be limiting. For example, the words "upwardly", "downwardly", "rightwardly" and "leftwardly" will refer to directions in the drawings to which reference is made. The words "inwardly" and "outwardly" will refer to directions toward and away from, respectively, the geometric center and designated parts of thereof. The word "distally" will refer to the direction towards the end of the arrangement located closest to the patient, and the word "proximally" will refer to the direction towards the end of the arrangement located remote from the patient. Said terminology will include the words specifically mentioned, derivatives thereof, and words of similar import.

DETAILED DESCRIPTION

Referring to FIGS. 1 and 2, a suture anchor and inserter arrangement 10 is illustrated which is generally elongated in shape and defines a central longitudinal axis "A". The arrangement 10 generally includes a suture anchor 11 initially supported on an inserter device 12. Working sutures 13 extend through the inserter device 12 and cooperate with a suture-engaging structure 14 carried on the suture anchor 11, which suture-engaging structure 14 is fixed to the suture anchor 11 independently of any insert molding process.

The inserter device 12 is defined by an elongate and rigid inserter shaft 16 having a distal end 17 which engages the suture anchor 11, and a proximal end 18 fixed to a handle 19. Inserter shaft 16 includes a tubular sidewall 20 which defines a bore 21 extending throughout the longitudinal length of shaft 16 (FIG. 5). Handle 19 has an outer surface defining therein a series of axially or longitudinally extending recesses or depressions 22, wherein each circumferentially adjacent pair of recesses 22 are separated by a longitudinally extending projection 23. The alternating recesses 22 and projections 23 provide the handle 19 with a suitable gripping surface similar to a screwdriver for use when manipulating the arrangement 10 with the hand.

As best shown in FIGS. 3 and 4, handle 19 includes a generally annular flange 24 which defines the most proximal terminal end of handle 19. An annular recess 25 is located axially adjacent and distally of flange 24. Handle 19 defines therein a bore including a proximal bore portion 29 opening proximally or axially through flange 24, and a distal bore portion 30. Distal bore portion 30 is in communication with, and has a lesser diameter than, proximal bore portion 29 and extends distally therefrom throughout the longitudinal extent of handle 19 for communication with bore 21 of inserter shaft 20. Handle 19 additionally includes a transversely oriented wall 31 which defines the terminal distal extent of proximal bore portion 29, and through which wall 31 distal bore portion 30 opens for communication with proximal bore portion 29.

In the illustrated embodiment, a pair of slots 32 which cooperate with free ends of working sutures 13 are provided within the proximal end of handle 19 diametrically opposite one another. Slots 32 as shown are identical to one another, and only one of same will accordingly be described herein. Slot 32 opens sidewardly outwardly through an outermost

4

side surface 33 of flange 24, axially through a terminal proximal end surface 34 of flange 24, and sidewardly inwardly for communication with proximal bore portion 29. Further, slot 32 extends distally a short distance from flange 24 so as to communicate with and open into annular recess 25 of handle 19.

With reference to FIG. 5, the distal end 17 of the inserter shaft 16 mounts thereon a projection 40. In the illustrated embodiment, projection 40 is polygonal in configuration so as to engage with the proximal end of the suture anchor 11. In one embodiment, the projection 40 has a rectangular cross-section. Projection 40 defines therein a centrally-located bore 41 which communicates with bore 21 of inserter shaft 16. It will be appreciated that other configurations of projection 40 are within the scope of the instant invention.

Turning now to suture anchor 11 as shown in FIGS. 6-10, same includes a generally elongate anchor body 50 defining a distal end 51 which is the end first inserted into the bone and a proximal end 52 associated with the distal end 17 of inserter shaft 16. A bore 53 centered on longitudinal axis A is defined within anchor body 50 and includes a distal portion 54 which terminates at an end face 55 and a proximal portion 56 which opens outwardly through the proximal end 52 of anchor 11. In the illustrated embodiment, proximal portion 56 of bore 53 is of a complementary polygonal profile as projection 40 of inserter device 12.

With reference to FIG. 9, anchor body 50 additionally defines therein a pair of transversely oriented passages which communicate with central bore 53 and open outwardly through the outer surface of body 50. Specifically, a first passage 57 extends in a generally transverse or radial manner from a distal region of distal bore portion 54 and opens outwardly through outer surface of anchor body 50. A second passage 58 is disposed in axially and circumferentially-spaced relation from first passage 57. Passage 58, which is the larger of the two passages, extends generally radially or transversely from a proximal region of distal bore portion 54 and opens outwardly through the outer surface of body 50. In the illustrated embodiment, passages 57 and 58 are diametrically opposite one another (i.e. about 180° from one another) on anchor body 50. However, passages 57 and 58 may be located at greater or lesser circumferential distances from one another along anchor body 50.

Anchor body 50 terminates at the distal end 51 in a tip portion 60 which is conical in configuration and includes a point 61 which defines the most distal end of the anchor body 50. In one embodiment, a pair of flutes 62 are defined in tip portion 60 diametrically opposite one another, and serve as cutting edges and for clean-out purposes, as is conventional. Further, a continuous thread 63 wraps around anchor body 50, which starts at proximal end 52 and terminates just axially short of tip portion 60.

With reference to FIGS. 8 and 9, anchor body 50 is of a cylindrically stepped configuration, and the outer diameter of such configuration steps downwardly or lessens in the direction from the proximal end 52 to the distal end 51. More specifically, this stepped configuration is defined by a first proximal and cylindrical stepped section 64 having the largest outer diameter of body 50. A second generally centrally located stepped section 67 is disposed axially adjacent stepped section 64, and is of a lesser diameter than section 64. A third generally centrally located and cylindrical stepped section 70 is disposed axially adjacent section 67 and is of a lesser diameter than section 67. A fourth distal and cylindrical stepped section 72 is located axially between section 70 and tip portion 60 and is of a lesser diameter than section 70. The tip portion 60 is located distally of section 70, and defines the

5

portion of anchor body **50** having the smallest outer cylindrical diameter. Further, the thickness of thread **63** at the outer diameter thereof, starting at approximately midway along anchor body **50**, increases as the thread **63** extends proximally.

FIGS. **6-10** illustrate the working sutures **13** attached to the suture anchor **11**. In this regard, suture anchor **11** carries thereon the suture-engaging structure **14**, which effectively serves as an attachment point for the working sutures **13**. In the illustrated embodiment, the suture-engaging structure **14** is defined by suture material which is fixed to the anchor body **50**. Specifically, a small length of suture material extends from distal portion **54** of central bore **53** outwardly through passage **57**, across the exterior surface of anchor body **50**, and then back into passage **58** and distal bore portion **54**. The opposite free ends of the length of suture material are then tied together to form a knot **81**, and this knot **81** may be located within passage **58** or alternatively within central bore **53**. In one embodiment, adhesive **89** may be utilized to reinforce and further secure knot **81**. In this regard, various types of biocompatible adhesives which may be utilized to secure knot **81** are cyanoacrylates, such as Histoacryl (an n-butyl cyanoacrylate distributed by TissueSeal LLC), ethyl cyanoacrylate, butyl cyanoacrylate, and octyl cyanoacrylate. Polycaprolactone (PCL), Poly-L-lactide acid (PLLA), and polyglycolic acid (PGA) may also be utilized.

The suture material thus forms a closed loop **82** having an interior section **83** located interiorly of the anchor body **50** and an exterior section **84** located exteriorly of the anchor body **50**. In this regard, exterior section **84** extends circumferentially about anchor body **50** between passages **57** and **58** within and along a portion of stepped section **67**. The stepped section **67** of anchor body **50** located between two adjacent thread flights of thread **63** thus defines a sidewardly-opening and circumferentially extending groove **80**. Groove **80** extends along an angle of at least about 90°, and in the illustrated embodiment extends along an angle of about 180°.

As best shown in FIG. **9**, the free ends of working sutures **13** extend into the proximal end **52** of the anchor body **50** into central bore **53**, loop around or over the interior section **83** of loop **82**, and then extend proximally back out of the anchor body **50**. Loop **82** thus defines a non-rigid or soft structure which is fixed to anchor body **50** and utilized to define an attachment point for the working suture **13**.

In the illustrated embodiment, two strands of suture define loop **82**. However, it will be appreciated that suture loop may be defined by a single strand **87** of suture material as shown in the embodiment of FIG. **15**, or triple strands **88** of suture material as shown in the embodiment of FIG. **16**. In this regard, it may be desirable to use a single strand **87** of suture material to form loop **82** if such material has sufficient strength, so as to simplify assembly, minimize materials, and reduce the volume of suture material within anchor body **50**. Also, it may be desirable to use triple strands **88** if the suture material utilized has a smaller diameter but is not of sufficient strength such that additional strands are necessary.

One method of assembling the suture anchor **11** onto the inserter device **12** is as follows. Free ends of two separate working or repair sutures **13** are inserted into the proximal end of inserter device **12** through proximal bore portion **29**, into distal bore portion **30**, through inserter shaft bore **21** and through bore **41** of projection **40**. These free ends of the working sutures **13** are inserted into bore **53** at the proximal end of suture anchor **11**, over the interior section **83** of suture loop **82** and then brought back out of the anchor bore **53** and back through the distal end **17** of inserter device **12** until same emerge at proximal bore portion **29** thereof. Alternatively,

6

instead of utilizing two pairs of working sutures **13**, a single working suture could be engaged with suture loop **82**. Three or more working sutures could also be utilized.

The bore **53** which opens at the proximal end of anchor **11** is circumferentially or rotationally aligned with the projection **40** of inserter device **12** at the distal end of inserter shaft **16**, and the projection **40** is inserted into the bore **53**. The free ends of the working sutures **13** located adjacent handle **19** are then pulled in a proximal direction so as to tension the working sutures **13**, and the working sutures **13** may then be pulled transversely or sidewardly relative to handle **19** to engage the working sutures **13** within one of the slots **32** so as to maintain the sutures **13** in a fixed position relative to inserter device **12**. If desirable or necessary, for example for storage purposes, the free ends of working sutures **13** may be wrapped or coiled around handle **19** and stored within annular recess **25**, and the free ends fixed in place within the opposite slot **32**.

The suture anchor **11** is intended for implanting within hard tissue, such as bone **90**. One method of implanting anchor **11** will be described with reference to FIGS. **11-14**. In some implanting procedures, i.e. when the suture anchor **11** is constructed of a hard material such as titanium, the anchor **11** is self-tapping, and thus no hole need be pre-formed in the bone **90** to insert the anchor **11**. With this type of anchor, with the suture anchor **11** installed on the inserter device **12** as discussed above, the tip portion **60** of the anchor **11** is placed in position relative to the bone **90** and the anchor **11** is rotatably driven into the bone **90** utilizing device **12** (FIG. **11**). Once the anchor **11** is located at the desired depth within bone **90**, the inserter device **12** is pulled in a proximal direction away from the anchor **11** (FIG. **12**) to unseat the anchor **11** therefrom. In this regard, the working sutures **13** would be released from slot **32** of handle **19** prior to the aforementioned step, so as to allow working sutures **13** to move freely relative to the inserter device **12** as the anchor **11** is deployed therefrom. Continued movement of the inserter device **12** in a proximal direction frees the working sutures **13** from the device **12**, so that the surgeon can use the sutures **13** to anchor soft tissue **92** to the bone **90**.

As shown in FIG. **13**, the surgeon utilizes a suitable surgical tool **93** to grasp one of the working sutures **13** and pull same through the soft tissue **92**. The same step is performed with the opposite working suture **13**. The two free ends of each of the working sutures **13** now extend around and through a portion of the soft tissue **92**, and the surgeon forms sliding knots **95** in the working sutures **13**. The knots **95** are moved down the working suture **13** to cinch the soft tissue **92** against the bone **90** at the location of anchor **11** (FIG. **14**). Any excess length of each working suture **13** may then be removed, if necessary. Once the suture anchor **11** is seated within the bone **90**, the stepped diameter of central body **50** of anchor **11** is believed to prevent improved resistant to proximal movement of the anchor **11** out of bone **90** so that the anchor **11** will remain firmly fixed therein. Further, the increasing thickness of thread **63** in the distal to proximal direction of the anchor as discussed above is also believed to provide improved pull-out resistance.

It will be appreciated that when the suture anchor **11** is constructed of softer materials, such as plastic, it is typically necessary to utilize a tap instrument to form a pre-formed hole in the bone **90**. In this regard, the tap instrument has a pointed tip which initially punches through the bone **90**, and has a threaded body located proximally of the pointed tip. The tap instrument is thus rotated relative to the bone so that a pre-formed threaded hole is defined in the bone **90**. The tip portion **60** of the anchor **11** is then aligned with this hole, and the anchor **11** is rotatably driven into the bone **90**.

The arrangement as discussed above includes the projection **40** on the distal end **17** of inserter device **12** which cooperates with the proximally-opening bore **53** of the suture anchor **11**. It will be appreciated that this configuration could be reversed, for example, the suture anchor **11** could include a projection or external drive head which engages within a corresponding recess formed in the distal end of the inserter device **12**. However, forming the anchor **11** with an internal construction for allowing cooperation with the inserter device **12** is believed advantageous as compared to conventional anchors which include externally projecting drive heads at their proximal ends. In this regard, configuring the anchor in this manner allows same to be made smaller, so as to cause less trauma to the patient, and also allows the anchor to be provided with a greater thread length within the available anchor length, and thus is believed to result in a better engagement of the anchor within the bone.

In addition, the cylindrically stepped configuration of the anchor body which decreases from the proximal end of the anchor towards the distal end is believed to provide improved pull-out resistance, as compared to conventional anchors having anchor bodies with a linearly tapered configuration.

The suture anchor **11** according to the invention may be constructed of any suitable rigid material, such as plastic or metal, and also may be constructed of bio-absorbable material or non-absorbable material. In this regard, one example of nonabsorbable plastic which may be utilized is PEEK, and one example of nonabsorbable metal which may be utilized is titanium. One example of an absorbable plastic which may be utilized is PLLA. Composite materials may also be used for both bio-absorbable and non-absorbable applications, such as PLLA/HA, which is a type of ceramic. It will be appreciated that other types of materials may be utilized in accordance with the invention, and the above are presented only as examples.

Additionally, the suture anchor **11** may have a length dimension of about 17 mm, and may have an outside diameter of about 5.5 mm or 6.5 mm. These dimensions are presented only as an example of relative dimensions of anchor **11**, and are not to be limiting.

Referring now to FIGS. **17-20**, a further embodiment of the suture anchor and inserter arrangement **110** is illustrated. The arrangement **110** includes a suture anchor **111** and an inserter device **112**. Components which are similar or identical to components described above in previous embodiments are provided with the same reference number, plus 100.

The inserter device **112** includes a projection **140** at a distal end **117** thereof. The shaft **116** and projection **140** of the inserter device **112** include a centrally located bore **141** through which working sutures **113** are passed, as described above. A single working suture **113** is illustrated for clarity, but multiple working sutures can be used and are within the scope of the invention. In the alternative, suture anchor arrangements are known which integrate a suture/needle combination. The common curved needle configuration precludes passage of the suture through a cannulated inserter device **112**. Therefore, a non-cannulated inserter or a partially cannulated inserter (not shown) in such an application would be compatible for use with the suture anchor **111**, with the working suture **113** passing on the exterior surface of the inserter device.

In the illustrated embodiment, the suture anchor **111** has a body **150** formed of a bio-absorbable material, such as PLLA, discussed above. The body **150** includes a distal end **151** and a proximal end **152** through both of which ends **151**, **152** a central bore **153** opens. Anchor body **150** additionally includes externally formed double-helix threads **163** running

the length thereof and having a generally uniform thread diameter. The distal end **151** of the anchor body **150** tapers inwardly in the proximal to distal direction, and includes a central opening **165** which communicates with or is contiguous with the central bore **153**. The threads can also be formed as a single helix (not shown) and fall within the scope of the invention.

The central bore **153** has a first or proximal bore portion **156** which extends from the proximal end **152** of the anchor body **150** to a distal end **154** located just proximate of the distal end **151**, and a second or distal bore portion **159** which extends axially from distal end **151** to distal end **154** of bore portion **156**, and has a lesser diameter than bore portion **156**. Further, bore portion **156** has a cross-sectional profile which matches the external configuration of the projection **140** of the inserter device **112**. The projection **140** is likewise configured for full-length insertion into bore portion **156** of bore **153** of the suture anchor body **150**, and in the illustrated embodiment has a square profile. The projection **140** can also have other profiles, such as hexagonal, oval, or star-shaped, and remain within the scope of the invention.

A pair of passages **157**, **158** extend transversely relative to the longitudinal axis **A** of the anchor **111**, from within the bore portion **159** of the central bore **153** to the exterior of the anchor body **150**. The passages **157**, **158** open outwardly into a circumferential groove **180** defined in the exterior surface of the anchor body **150**, which groove **180** extends around the entire circumference thereof.

In order to form a soft eyelet for engaging the working sutures **113**, a single strand of suture material **179** is passed through passages **157**, **158** so that it extends through bore portion **159** and transversely to the longitudinal axis **A** of the anchor body **150**, as shown in FIG. **20A**. Each end **194**, **191** of the suture material **179** is drawn 180° around the body **150** in the circumferential groove **180** (FIG. **20B**) and inserted through the respective opposite passage **157**, **158** back into bore portion **159** (FIG. **20C**). The ends **194**, **191** are then drawn outwardly through the opening **165** in the distal end **151** of the anchor body **150** and secured to one another, such as by a knot **181** (FIG. **20D**), or as described above. The working suture **113** is loaded into inserter device **112** as discussed above, and the free end is drawn out from bore **141**. The free end of working suture **113** is then drawn through the central bore **153** of the suture anchor **111** through distal end **154** to capture at least one of the two "passes" of the suture material **179** (FIG. **20E**), which now form a loop **182**. As tension is placed on the loop **182** by the working suture **113**, the knot **181** is drawn into the opening **165**, and the loop **182** is drawn into proximal bore portion **156** of the central bore **153**. The free end of the working suture **113** is then drawn back through the central bore **141** of the inserter device **112**.

The projection **140** is inserted into the proximal bore portion **156** of central bore **153** of the suture anchor **111** until the projection **140** extends the full depth of the bore portion **156** to distal end **154**. The projection **140** thereby fully supports the length of the suture anchor **111**, and increases the bearing surface between the projection **140** and the central bore **153** of the suture anchor **111**. A given force is necessary to drive the suture anchor **111** into bone. The increased bearing surface between the projection **140** and the suture anchor **111** distributes this force over a greater area, thereby diminishing the shearing force exerted on the material of the anchor body **150**. The projection **140** further provides full length support of the hollow suture anchor **111** to prevent its collapse during insertion into a pre-tapped hole in the bone. In the illustrated embodiment, the anchor **111** is not self-tapping and is pro-

vided with tapered distal end **151**, and thus requires a pilot hole be prepared in the bone before insertion.

The anchor **111** is implanted in bone in a manner similar to that described above.

Although particular preferred embodiments have been disclosed in detail for illustrative purposes, it will be recognized that variations or modifications of the disclosed apparatus, including the rearrangement of parts, lie within the scope of the present invention.

What is claimed is:

1. A suture anchor arrangement comprising a suture anchor, said suture anchor including an anchor body having a longitudinal axis, a distal end configured for implanting into hard tissue and a proximal end spaced from said distal end, said anchor body defining therein a continuous bore extending from said proximal end to said distal end and opening axially through said distal end, a pair of passages each opening into said bore and communicating therewith, and a length of working suture for securing soft tissue to said anchor body, said anchor body including a suture-retention interface defining an attachment location on said anchor body for attachment of said working suture to said suture anchor, said interface including a loop having a first part extending from one said passage to the other said passage entirely within said bore, said first part of said loop defining said attachment location which is disposed entirely within said bore, said working suture being attached to said first part of said loop within said bore to interconnect soft tissue to said anchor body when said anchor body is installed within hard tissue, and said loop having a second part extending between said passages outside said bore, said second part of said loop extending along an exterior of said anchor body in a circumferential direction about the axis and between said passages.

2. The suture anchor arrangement of claim **1**, wherein said loop is formed from suture material, and said loop has a pair of terminal free ends which are secured to one another such that said loop comprises a closed and continuous loop of said suture material fixed to said anchor body.

3. The suture anchor arrangement of claim **2**, wherein said terminal free ends of said loop are tied to one another to form a knot, said knot being disposed within said bore proximate said distal end.

4. The suture anchor arrangement of claim **1**, wherein said bore extends in a direction generally parallel with the longitudinal axis of said anchor body, and said passages are oriented transversely relative to said bore.

5. The suture anchor arrangement of claim **4**, wherein said anchor body has a threaded exterior surface for engagement within a cavity defined in bodily tissue, and said bore defines a recess configured for engagement with an inserter device for facilitating insertion of said suture anchor into tissue, said recess opening proximally through said proximal end of said anchor body and extending from said proximal end substantially to said passages.

6. The suture anchor arrangement of claim **1**, wherein said anchor body has an exterior surface and each said passage opens outwardly through said exterior surface through an outer end, said outer ends being radially aligned with one another along a line which extends through the longitudinal axis.

7. The suture anchor arrangement of claim **1**, wherein said interface comprises a closed and continuous loop of suture material which is fixed to said anchor body independently of any insert molding process.

8. The suture anchor arrangement of claim **1**, wherein said exterior of said anchor body includes an outer surface defining a circumferential groove therein in which said second part of said loop is disposed.

9. The suture anchor arrangement of claim **8**, wherein said passages extend transversely to the longitudinal axis so as to open inwardly into said bore and outwardly into said groove, said second part of said loop occupying a portion of said groove.

10. The suture anchor arrangement of claim **9**, wherein said loop has a third part extending along said exterior of said anchor body and occupying a further portion of said groove on an opposite side of said anchor body from said second part.

11. A suture anchor arrangement comprising:
a suture anchor including an anchor body defining a longitudinal axis, said anchor body having a distal end configured for insertion into hard tissue and a proximal end spaced axially from said distal end, said anchor body defining therein a substantially axially-extending bore disposed within an interior of said anchor body, and a pair of passages extending through said anchor body each in a direction transverse to the axis, each said passage having an inner end which opens into said bore and communicates therewith and an outer end spaced radially from the respective said inner end and opening through an exterior of said anchor body, said outer ends of the respective said passages being axially aligned with one another and spaced circumferentially from one another along said exterior of said anchor body;
a length of working suture for securing soft tissue to said anchor body; and
a loop for securing said working suture to said anchor body, said loop having an interior portion disposed within said bore and extending between the respective said inner ends of said passages, said interior portion defining an attachment location for securing said working suture to said anchor body, said loop having an exterior portion extending circumferentially along said exterior of said anchor body between the respective said outer ends of said passages, said working suture being attached to said interior portion of said loop within said bore to interconnect soft tissue to said anchor body when said anchor body is installed within hard tissue.

12. The suture anchor arrangement of claim **11**, wherein said exterior portion of said loop is a first exterior portion and said loop includes a second exterior portion extending circumferentially along said exterior of said anchor body between the respective said outer ends of said passages, said first and second exterior portions extending along opposite sides of said exterior of said anchor body.

13. The suture anchor arrangement of claim **11**, wherein said loop comprises a closed, continuous and circular loop of suture material fixed to said anchor body and carried entirely on said anchor body so as not to extend axially beyond said proximal end thereof.

14. The suture anchor arrangement of claim **11**, wherein said loop comprises a closed and continuous loop of suture material distinct from said working suture and having a pair of terminal free ends secured to one another so as to form said closed and continuous loop.

15. A suture anchor arrangement comprising:
a suture anchor including an anchor body defining a longitudinal axis, said anchor body having a distal end configured for insertion into hard tissue and a proximal end spaced axially from said distal end, said anchor body

11

having a generally hollow interior and an exterior surface spaced radially outwardly from said hollow interior; and

an attachment structure fixed to said anchor body, said attachment structure including a closed and continuous loop having an interior portion disposed entirely within said hollow interior of said anchor body and first and second loop portions, each of said first and second loop portions having an exterior portion disposed outside of said hollow interior and extending circumferentially along said exterior surface of said anchor body, said first and second loop portions extending along said exterior surface in opposite directions from one another, said interior portion extending transversely across and entirely within said hollow interior to define an attachment location disposed entirely within said hollow interior for securing a working suture to said anchor body.

16. The suture anchor arrangement of claim **15**, wherein said attachment location is disposed adjacent said distal end of said anchor body, and said loop comprises a length of suture material having a pair of free terminal ends which are secured to one another such that said loop is a closed and continuous loop of suture material fixed to said anchor body and carried entirely on said anchor body so as not to extend axially beyond said proximal end thereof.

17. The suture anchor arrangement of claim **16**, wherein each of said exterior portions of said first and second loop

12

portions extend circumferentially about the axis in opposite directions from one another and along diametrically opposite sides of said exterior surface of said anchor body.

18. The suture anchor arrangement of claim **16**, wherein said anchor body defines therein a pair of passages extending through said anchor body adjacent said distal end thereof and being oriented transversely relative to the axis, each said passage having an outer end which opens outwardly through said exterior surface of said anchor body and an inner end which opens inwardly into said hollow interior, said first and second loop portions extending through said passages such that said exterior portions thereof extend outwardly and out of said hollow interior through said outer ends of said passages, said exterior portions of said first and second loop portions extending circumferentially about the axis in opposite directions from one another and along diametrically opposite sides of said exterior surface of said anchor body.

19. The suture anchor arrangement of claim **15**, wherein said hollow interior opens axially through both said proximal and distal ends.

20. The suture anchor arrangement of claim **15**, further including a working suture secured to said interior portion of said loop to interconnect soft tissue to said anchor body when said anchor body is installed within hard tissue.

* * * * *